Margins of Stability in Children with Cerebral Palsy Diplegia: Barefoot versus AFO Comparison

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INTRODUCTION

Research of children with Cerebral Palsy (CP) indicates poorer balance than normal (Hsue 2009). Ankle-foot orthoses (AFOs) are often prescribed to improve balance, but little research confirms their effectiveness. The use of the extrapolated center of mass in calculating the margin of stability (MoS) provides a more accurate measure of dynamic balance (Hof 2005). No studies have used this method to determine the effect of AFOs on the dynamic balance of children with CP diplegia using AFOs. This study attempts to do this.

METHOD

Subjects: Gait data from 191 children (129 male, 62 female) with CP diplegia were analyzed. These children were tested using their own bilateral custom molded thermoplastic AFOs, which were hinged, posterior leafspring (PLS) or solid ankle style.

Apparatus: Marker trajectory data were used to calculate the extrapolated center of mass (XCoM). The average normalized mediolateral (ML) and backward (BW) MoS were calculated at midstance and initial contact, respectively. Four pendulum lengths (calculated and measured leg length, maximum and midstance center of mass (COM) height) were compared to determine measure sensitivity. Normalization by leg length was examined.

Procedures: This is a retrospective analysis of gait data collected between 1994-2012 at Gillette Children's Specialty Healthcare Center for Gait and Motion Analysis as part of routine clinical care. This study received IRB approval.

Data Analysis: Data were analyzed using MATLAB. ANOVA with post hoc Tukey-Kramer test for significance, paired t-tests, and linear regressions were used for statistical analysis with significance level of $p < 0.05$.

RESULTS

Pairwise comparisons for each combination of MoS, pendulum, and AFO type were completed. Pendulum lengths differed from each other, but the resultant MoS did not. The MoS increased with subject height, but not when normalized by leg length. Comparisons of all subjects' AFO and barefoot normalized MoS indicated that the ML MoS was significantly smaller and BW MoS significantly greater with AFO use for all subjects. When repeated for each AFO type, similar results were found for BW, but not ML, MoS.

DISCUSSION

The MoS is a robust measurement that is not sensitive to the pendulum length used. This indicates that studies are comparable. Although previous studies of adults did not normalize the MoS, this study found that it was necessary for children.

Smaller ML and larger BW MoS were observed. Since a significant difference was found for all subjects', but no AFO subgroups', ML MoS and because the order of magnitude was millimeters, this is not likely a clinically meaningful result. The difference is likely due to the large subject pool. The increase in BW MoS with AFO use is considered clinically significant as the effect was seen for all comparisons and the order of magnitude is centimeters. The BW Mos is important when transitioning weight from one limb to the other for fall avoidance. A future prospective study that standardizes the AFO prescription and fabrication, as well as footwear is necessary to determine the cause of this change. The authors are currently examining the barefoot MoS for typically developing children to deterine whether or not the increase in BW MoS is bringing the children with CP closer to normal.

CONCLUSION

The MoS is resilient to pendulum type used and requires normalization. An increase in BW, but not ML, MoS was observed with the use of AFOs for children with CP diplegia.

CLINICAL APPLICATIONS

AFOs appear to increase the BW MoS or room for error that children have in the anterior-posterior direction, which may allow them to better adapt to perturbations while walking and thereby reduce falls.

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Effect of Daily Limb Volume Changes and Volume Accommodation on Activity and Self-Reported Outcomes

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INTRODUCTION

People with trans-tibial limb loss typically experience changes in residual limb volume while performing activities such as standing, walking, and sitting (Sanders 2014). The resulting fluctuations degrade prosthesis fit and require accommodation strategies such as donning prosthetic socks. The purpose of this study was to examine how normal activities and self-reported outcomes relate to daily changes in residual limb volume and volume accommodation.

METHOD

Subjects: Volunteers with trans-tibial amputation wearing a normal prosthesis participated.

Procedures: Over a two week interval of normal daily activity, subjects documented their daily sock changes (D'Silva 2014). Subjects then completed a three-part, in-lab session over a single day.

On the morning of the in-lab session, subjects completed the SCS (Hanspal 2003) and select subsections of the PEQ (Legro 1998). Next, subjects underwent a 35-minute controlled protocol while limb fluid volume was measured by a bioimpedance analyzer (Sanders 2015). Two 3-axis accelerometers (wGT3X+, Actigraph) were then attached to the subject's prosthesis, and they left the lab to conduct their normal daily activities for at least three hours. Subjects then returned to the lab in the afternoon, and the morning bioimpedance protocol was repeated.

RESULTS

Twenty-seven subjects were classified into two groups using their self-reported sock use. Accommodators (n=12) changed socks at least once, while non-accommodators (n=15) made no changes. During the monitored period between in-lab sessions, accommodators spent 6% more time weight bearing (walking or standing), while non-accommodators spent 10% more time with the socket doffed. Further, non-accommodators reported higher scores in each survey category with the highest difference of 1.1 (0-10 scale) in the SCS (Figure 1).

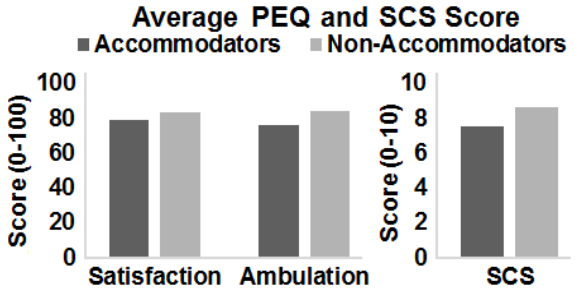

Figure 1. Average PEQ (satisfaction and ambulation) and SCS results for accommodators and non-accommodators.

In-lab bioimpedance data showed that about 80% of participants in each group lost volume over the day. Doffing during the three hour period between sessions produced the strongest correlation to volume change (r=0.49). Bouts of sitting and standing were negatively correlated to anterior volume change, while ambulating was negatively correlated to posterior volume change. SCS, PEQ-satisfaction, and PEQ-ambulation subscales positively correlated with volume change (mean 0.17 ± 0.09, Table 1).

Table 1.Pearson correlation coefficient comparing volume change to activity distribution and survey results.

	Volume Change	Anterior	Posterior
Activity	Doffed	0.49	0.37
	Sitting	-0.30	-0.04
	Standing	-0.26	-0.07
	Walking	0.03	-0.31
	Weight Bearing	-0.08	-0.29
Survey	Comfort	0.26	0.27
	Satisfaction	0.18	0.16
	Ambulation	0.16	0.03

DISCUSSION

Participants who accommodated with prosthetic sock adjustments were not significantly more active and did not report higher satisfaction, comfort, or ambulation scores. The difference in time doffed between the two groups suggests that those labeled as non-accommodators may have been choosing to compensate volume loss in an alternative fashion. The positive correlation between doffing and volume change may help explain why non-accommodators spent more time doffed while choosing not to make sock adjustments. The correlation between SCS and volume change also suggests that minimizing volume loss throughout a day may lead to increased user comfort.

CLINICAL APPLICATIONS

While prosthetic socks are commonly used to improve socket fit, previous studies have shown that it can be difficult to predict the accommodation they provide (Cagle 2015). This may explain practical differences seen in self-reported scores between accommodators and non-accommodators. Results from this study suggest that integrating doffing as a normal accommodation strategy may increase user comfort and satisfaction.

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An Interim Analysis of the Use of Virtual Reality to Enhance Upper Limb prosthetic Training and Rehabilitation

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INTRODUCTION

Approximately one in every 160 Americans are currently living with an amputated limb. There are nearly 2 million people with a limb loss in the United States, with around 50,000 new amputations occurring each year. The sudden loss of a hand or arm causes the loss of fine, coordinated movements of the upper limb, reduced joint range of motion, tactile sensation, reduced proprioceptive feedback and aesthetic appearance, all which can be improved with the use of a prosthesis. Maintenance of joint range of motion, increasing upper-limb muscle strength, and gaining maximal functional independence are all crucial elements to ensure patient success with the prosthesis, making the training and rehabilitation phase significantly important. An effective training and rehabilitation program allows patients to return to their daily life duties at the most functional independence possible with the use of all prosthetic control capabilities. Since a successful training and rehabilitation program is essential, the need for advanced rehabilitation techniques is substantially high.

METHOD

Subjects: The patient population for this study included healthy individuals (n=5) and individuals with a unilateral transhumeral or transradial amputation who used a body powered or myoelectric prosthesis (n=10).

Apparatus: The Computer Assisted Rehabilitation Environment (CAREN) system (Motek Medical, Netherlands) was used to immerse patients into real life situations while providing real time visual feedback of their motion. CAREN is a multimodal system consisting of a 10-camera real time motion capture system (Vicon, Nexus, Englewood, CO), with a 6 degree of freedom hydraulic base with a double-belted instrumented treadmill and a 180-degree cylindrical screen projection system.

Procedures: Prior to participation, all subjects signed an informed consent. Specific anatomical measurements were taken and 40 reflective markers were placed at precise points on the subject. Each subject participated in two sessions, one with the use of virtual reality and one without. The order each subject completed the sessions was predetermined by a random generator. Each session lasted 1-2 hours, consisting of a series of range of motion (ROM) tasks, activities of daily living (ADL), and return to duty (RTD) tasks. When using the virtual reality, subjects were shown their real time avatar simultaneously with the individualized optimal motion for each task. Each task was completed three times.

Data Analysis: The motion-captured data of each subject were used to directly calculate the kinematic model's joint angles from the measured XYZ marker positions on a frame-by-frame basis. The elbow, glenohumeral, and torso angle ROMs were all found. The joint angle ROMs were also calculated from optimal motion analysis data for a measure of comparison.

RESULTS

Greater improvements in movement and ROM were evident in subjects when using the virtual reality system verses non-virtual reality training. Improvements were assessed between each succeeding trial while using the virtual reality system and subject's movement quickly became closer to the optimized goal motion showing movements to significantly improve.

DISCUSSION

Preliminary results suggests training and rehabilitation for upper limb prosthetic users are enhanced through improved movement and joint ROM when provided visual feedback of the subject's real time avatar and an optimal goal motion model with the use of virtual reality.

CONCLUSION

The enhancement of upper limb prosthetic training and rehabilitation is especially beneficial to improve user's movement, joint angle range of motion, and overall quality of life while greatly contributing to the state of science.

CLINICAL APPLICATIONS

With effective training and rehabilitation, prosthetic users are able to gain the maximal functional level of independence possible. This will be clinically significant to upper limb prosthetic training and rehabilitation programs by introducing an adaptable way to increase effectiveness and greatly impact the future of prosthetic users.

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A CASE SERIES STUDY OF PATTERN RECOGNITION FOR UPPER-LIMB PROSTHESIS CONTROL

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INTRODUCTION

Traditionally, myoelectric control of a prosthesis uses two antagonistic muscles. Users must learn to use their muscles independent of each other, often to produce motions that are not normally associated with that muscle contraction. As electrically powered prostheses become more complex, a more intuitive and reliable method of prosthesis control is required.

Pattern recognition could eliminate the need for complicated programming and adjustments. It may even allow individuals with poor myoelectric signal separation to use a myoelectric prosthesis since finding isolated myoelectric control sites is not necessary. With pattern recognition, multiple electrodes are placed on the skin to detect coordinated muscle activity. Successful pattern recognition allows the user to make natural intuitive movements to control corresponding prosthesis movements. Reported is the first independent, clinical case series implementing pattern recognition. It was conducted across multiple centers to a diverse patient population. This case series study provides initial evidence that pattern recognition can be implemented in standard prosthetic practices and is equal to or superior to conventional myoelectric control.

METHOD

This is an observational, interview study of prothetists' and patients' experience in fitting, implementation, and use of pattern recognition systems. Experience from 10 prosthetists and 14 patients in Hanger's Upper Extremity Prosthetics Program are reported. CoAPT Complete Control Systems (CoAPT LLC, Chicago, IL) systems were implemented. Subjects included male and female amputees. Amputation levels fitted include: shoulder disarticulation, trans-humeral, trans-radial, and wrist disarticulation. Two subjects had congenital limb deficiency. Five subjects had targeted muscle re-innervation (TMR) procedures.

RESULTS

In all cases, pattern recognition was found to have advantages over 2 site conventional control. User comments included: Faster response time, better proportional control, shorter learning curve, and no need for co-contraction.

DISCUSSION

The consistency in our results was surprising given that despite a diverse patient population and multiple clinicians, pattern recognition was found to have advantages over 2 site conventional control in all cases. We would have thought that there would be some cases that there would not be any advantages.

Prosthesis use training seemed easier using pattern recognition compared with conventional dual site control. This was especially true for the patients who had received TMR surgery and for the congenitally limb deficient.

Prosthesis fabrication was only slightly more complicated as a result of the increased number of electrode inputs and the need to find space for the added electronics. It may be beneficial to incorporate the pattern recognition electronics into the native component control modules of elbows and hands in the future.

CONCLUSION

Pattern recognition can be implemented in standard prosthetic practices and is equal to or superior to conventional myoelectric control, offering an attractive advance in upper extremity prosthetics. Generally pattern recognition makes prosthesis control more intuitive.

CLINICAL APPLICATIONS

This review of our first pattern recognition control patients supports the hypothesis that pattern recognition control is easier to learn and more intuitive than conventional control methods. Pattern recognition makes prosthesis use more spontaneous, especially when combined with TMR surgery and for congenitally limb deficient individuals.

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Development of an Upper Limb Instructional Design to address Self-efficacy among self-assessed Novice and Intermediate Prosthetic Clinicians

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INTRODUCTION

The intent of this instructional design proposal is to increase personal clinical self-efficacy and competence with upper limb prosthetic fitting in order to improve the overall acceptance rate of upper limb prostheses among patients. More specifically, the educational goal is to decrease the skill gap and level of dissonance that seems to be broadening between the dichotomous Expert-Specialist (E-S) and the Novice -Intermediate (N-I) groups. In a recent on-line survey of 151 practitioners, 71.8% self -identified themselves as in the N-I group, while 26.2% identified themselves as part of the E-S group. The ultimate impact of this instructional design would be to increase the level of upper limb prosthetic competency and care and could serve as a model for other high tech components.

METHOD

After the telephone interviews and on-line survey an additional Relevant Characteristics of the Learner that drove the comparison of the Expert-Specialist (E-S) group could be compared to the Novice-Intermediate (N-I) Group with respect to the greater number of extrinsic professional linkages, attitudes toward innovation, and characteristics both groups felt contributed to becoming a specialist. These characteristics included Patient Experience, Interaction with and Expert, Familiarity with Component Design, Socket Design, Ability to Adjust the Prosthesis, and Dealing with Variation in the patient population. The instructional design process was engaged and the performance objectives were further refined to three main performance objectives. Differences between private and institutional settings revealed a major difference in the number of extrinsic professional linkages. Although the comparison of the data was limited in that it was not subjected to a t-test for distribution and formal correlation measures, it did seem to indicate that there was a higher degree of extrinsic social interaction, greater confidence, and a higher tolerance of innovative risk.

PERFORMANCE OBJECTIVES & JOB TASKS

The three main performance objectives identifies were 1) Increasing Extrinsic Heterophillic Linkages, 2) Providing more Access to Contextual Clinical Experts, and 3) Development of Self-Directed Educational Materials.Provide additional scaffolding to increase the level of practitioner confidence.well. reproduce well. The Job Tasks in Upper Limb Prosthetics were described to a greater degree with a value rubric in the Identification, Process and Function, and Clinical Practice of Evaluation, Impression Taking, Modification, Initial Fitting, Componentry Recommendation, Adjustment, and Final Delivery and Follow-up. The ability to outline these tasks would allow the construction of a self-efficacy measure similar to those proposed for nursing and anatomy students. The sequencing has become more detailed from the initial step-by-step procedure to a more appropriate “Part to Whole” and “Known-to-Unknown” sequencing where the learner will be able to successfully break down the issues surrounding upper limb fitting as well address some of their individual self-perceived inadequacy regarding upper limb fitting.

PERFORMANCE MEASURES & STRATEGIES

The first measure would be the number and quality of extrinsic heterophillc linkages since they appeared to be lower among the N-I group in the private clinics and much higher in the E-S group in the Institutional/Corporate setting. The number of extrinsic linkages should be increased to from the 1.75 linkages seen as an average of novices and intermediates to approximately 3.5 on average. The macro-institutional strategy would use access to the Internet to make a variety of information available in various settings, regions, and professional levels. Since prosthetic offices are often distributed over a wide range of regions, the strategy should have a national scope of delivery. Also it is important to create linkages that are cross regional to enhance the degree of cosmpolite and cross-cultural exchange. The micro-institutional strategy would consist of the development of three different components that would each emphasize access for personal references, social/professional linkages, and expert interaction. They would involve the creation of a number of upper limb learning modules that address the different levels of amputation.

INSTRUCTIONAL SEQUENCING

The instructional sequencing would be Initial Clinical Assessment, Introduction to Learning Materials, Completion of Targeted Reference Material, Discussion Board, Virtual Clinic Conference, and Final Assessment among groups of 5-7. Clinical independence will be fostered at the context of the learner with reference materials, on-line instruction, personal expert interaction, and simulated group clinical education..

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OPEN-SOURCE DEVICE FOR VARIABLE ULNAR EMINENCE

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INTRODUCTION

The availability and economy of current 3D printing technology is closing the gap between the availability of Personal Adaptive Devices (PAD) and those in need of PADs. Given a few conventional measurements, a 3D-printed glove can be made from simple, inexpensive filament thermoplastics within 24-hours. The advent of "Rapid Prototyping" are easy-to-fit, ready-to-use personal adaptive devices.

A 26 year old patient, (C. C.), has a congenital amputation of the left upper-extremity combined with variations in ulnar head prominence. Through the facilities at Florida Atlantic University (FAU), and assistance from Dr. Aaron Berger, we were able to build and refine a modified version of the Raptor II model that allows for greater ambidexterity.

Herein, we present the modifications of an open-source 3D model to demonstrate its versatility and potential clinical acceptability as a medical device option for those with upper-extremity congenital anomalies with variations in ulnar head prominence.

METHOD

Models were developed applying various CAD software packages in conjunction with "Open Source" models provided by the Enabling the Future group. This allows for the customization of each PAD. This is critical as each PAD is as unique as is each client served. Occupational evaluation resolved comfort issues by using readily available padding and cushioning including moleskin, wool packing and adhesive blue foam padding applied to Velcro straps.

Measurements for ulnar variance were taken in zero rotation, to adjust the scale in the CAD program for the Raptor II design. Our preliminary efforts demonstrated limited ambidexterity in patient, C.C., whose complex anatomy was hindered by the Raptor's initial design. Modeling determined the best fit was at 138% scale. Total print time was 12 hours. To address the patient's extension of the ulnar head prominence, recess modifications were also designed using CAD software.

RESULTS

Although preliminary use of the Raptor II design (Fig.1) gave patient C.C. limited ambidexterity, he was able to lift objects up to 30 pounds. Additional padding led to an increase in comfort and prevented skin breaks and frictional damage. However, after two months, C.C. felt significant discomfort due to muscle development as a result of extensive use. Further observation indicated the need to remove material from the Ulnar Prominence on the PAD itself (Fig. 2).

Fig. 1

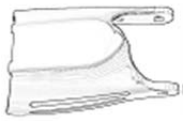

Fig. 2

Subsequently the patient showed greater dexterity and was more comfortable with the additional 2.1% scale and material recess which led to a greater ability to complete routine tasks including steering wheel control, bicycle riding, tying shoes, etc.

DISCUSSION

For providers, an ideal prosthesis is one that conforms to any patient; however this is challenged by patient growth or changes in medical condition(s). Our concept shows that this design can be easily modified and scaled to each patient and can be easily replaced or updated as needed by the patient.

Families typically face difficult financial challenges securing PADs for children due to cost and gaps in insurance coverage. Our approach which includes a collaborative community alleviates the financial stresses and difficulties while providing unfettered access.

This device also increases a patient's self-esteem and confidence. 3D printing has brought the discussion of disability out of the shadows. Young children perhaps embarrassed by their own appearance can now proudly display "the hand I designed."

CONCLUSION

We demonstrate a rapid prototyping process that enhances a versatile clinical application for custom hand prosthetics.

CLINICAL APPLICATIONS

This device has been shown to promote the use of unused, atrophied forearm extensor and flexor muscle groups. With additional padding and design modification(s), we can likely further decrease patient discomfort, risks for skin breaks and ulceration.

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Differences in Voluntary Closing and Voluntary Opening Terminal Devices in Transradial Amputees Measured with the Continuous Scale Physical Functional Performance-10 (CS-PFP10) Assessment

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INTRODUCTION

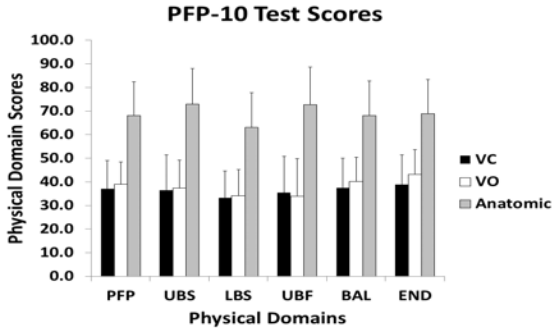
Functional studies of persons with transradial amputation (TRA) are limited. Studies comparing voluntary opening and voluntary closing body-powered prostheses are also limited. Entry-level prosthetic training material suggests VO systems have decreased grasp force but are preferred over VC systems. Conversely, VC systems reportedly offer higher grip force and enable kinesthetic feedback during manipulation and grasp but may increase the likelihood of fatigue. This study sought to determine if VO systems were functionally different than VC systems and if VO systems are preferred among TRAs.

METHOD

The study was approved by the USF IRB and listed in a federal clinical trial registry. A randomized, 2-period cross-over experimental design was used. A non-amputee control group was also studied. Unilateral TRAs who used body powered prostheses currently for ≥1y were recruited. Subjects were 18-85y and free of medical comorbidities. Non-amputees were also healthy, independently functioning persons of a similar age range. TRAs' preferred prostheses were evaluated and adapted to accept both a VO and VC terminal device (TD). Assignment to VO or VC were randomized. Subjects were provided a brief training and accommodation period prior to data collection. After data collection, TDs were crossed-over and the process repeated.

CS-PFP10 was administered via standardized procedure (i.e. certified test site, script dialogue, trained rater; all reported elsewhere). CS-PFP10 scores 10 ADLs in time, distance, and mass. Raw data reflects physiologic functional domains. Testing requires ≈30min. Raw data (time, distance, mass) are converted to summary scores with a validated algorithm in licensed software. Scaled from 0-100, summary scores include CS-PFP total score (CS-PFP TOT) and 5 physiologic domain scores: upper body strength (UBS) & flexibility (UBF), balance & coordination (BAL), lower body strength (LBS) & endurance (END). RPE following testing and preference of device were also assessed following testing.

Data were examined for normality. Paired *t*-tests were used for between-TD comparisons. Independent samples *t*-tests to compare TRA and controls when data (interval & ratio level) were normally distributed. Otherwise, Wilcoxon's Signed-Rank test for median differences was used (SPSS). Effect size(ES) was calculated using accepted methods and interpretations for Cohen's *d*. The *a priori* significance level was $p \leq 0.05$.



Values = mean±SD. No statistically significant differences were observed in any PFP score between VO and VC. All PFP score was $p \leq 0.05$ between TRA and controls.

RESULTS

8 TRAs (age: 56.1y±10.4; BMI: 26.7±3.6kg/m^2) and 10 controls (age: 23.6y±6.0; BMI: 25.2±2.1kg/m^2) completed the study. There was 1 female in each group. Age was greater in TRAs($p<0.01$) but BMI was similar between groups($p>0.05$). Four TRAs lost their hand to trauma and the remaining 3 were congenitally absent. Mean stump-sound forearm length ratio was 53%. Mean daily prosthetic use was 12.0±4.2hrs/day. Six TRA were employed and 2 were retired. Controls were university students.

Domain and total PFP scores ranged from 2.5-10.1% different between TD conditions but none were significantly different. Differences were on the order of 37-53% greater for controls compared to TRA ($p<0.05$; large effect) for all domains and total PFP regardless of TD. There were no significant differences in perceived exertion or preference between devices among TRA.

DISCUSSION & CONCLUSION

Information suggesting differences in function between VO and VC are not detected using the PFP test across upper and lower body domains or in total function. Further, there were not isolated differences in functional upper body strength, exertion or preference between devices. There were significant differences in function between non-amputee controls and TRA which objectively quantifies a degree of impairment associated with transradial amputation. It is noteworthy that controls were younger and this sample represented TRAs who prefer body-powered devices who are active. Different findings may result depending upon subject age, myoprosthetic use or other factors. Given the large differences between TRA and controls regardless of TD, room for functional improvement and developments for improved devices are emphasized.

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*Presenter

Does dynamic balance of transtibial amputees change after a three week adaptation period on a new prosthetic foot?

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INTRODUCTION

Balance during walking is of high importance to transtibial amputees (Legro, 1999) and its assessment is a fundamental consideration in prosthetic rehabilitation.

The margin of stability (MOS) is a measure of dynamic balance, adapted from traditional static base-of-support measures to account for center of mass (COM) motion during movement (Hof, 2004) via the addition of an inertial term, the Extrapolated Center of Mass (XcoM).

We hypothesized that changes in balance over a 3 week adaptation period with a new prosthesis would differ in the mediolateral (MOS_{ML}) and anteroposterior (MOS_{AP}) depending on the individual's prescribed Medicare functional level. Specifically, improvements in balance would be exaggerated when adapting to a foot of a lower activity level than that of the person's correct functional level.

METHOD

Subjects: 21 unilateral transtibial amputees (27-76 yrs; 1.78 (0.81) m; 100.6 (18.8) kg; etiology traumatic (n=13), vascular (n=5), other (n=3)) participated in a randomized crossover trial. All subjects were previously categorized as K3 or K4 and appropriately wore high activity feet with their personal prostheses.

Procedures: Participants were tested on two foot components rated 'higher activity' (HA) (i.e. energy-storage-and-return type feet) and 'lower activity' (LA) (e.g. SACH) with order of provision randomized. A new foot component was provided and aligned by a certified prosthetist at the initial session (V1) after which participants immediately undertook baseline gait assessment. Retroreflective markers on the lower limbs and pelvis were recorded during ten traverses at self-selected walking speed using a 12-camera motion capture system (60 Hz; Motion Analysis Corp.). After 3 weeks, participants returned for a repeat assessment (V2). The foot component was then swapped for the other category foot and the process (V1, V2) was repeated.

Data analysis: Pelvis and foot markers were used to estimate COM (Hak, 2012) and base of support respectively. MOS_{ML} was defined as the minimum distance between the XcoM and the lateral margin of the base of support during movement (Hof, 2004) while MOS_{AP} was the maximum distance that the XcoM was allowed to progress past the base of support prior to heel strike of the contralateral limb. MOS_{ML} and MOS_{AP} were examined using a three way repeated measures ANOVA (leg x prosthesis x visit) with Fisher's LSD post hoc tests.

RESULTS

MOS_{AP} was greater on the sound limb compared to the prosthetic limb for the LA foot. There were significant increases in MOS_{AP} for both limbs from V1 to V2 for the HA foot (Figure 1a). Non-significant changes in MOS_{ML} for the HA foot resulted in the elimination at V2 of a significant interlimb difference previously recorded at V1. No such change was seen with the LA foot (Figure 1b).

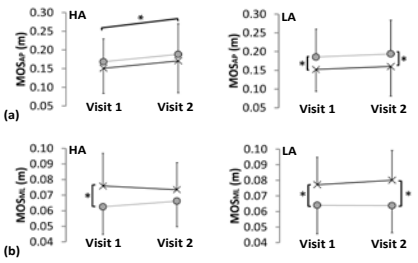

Figure 1. Margin of stability (MOS) across visits (a) Anteroposterior (AP), (b) Mediolateral (ML). HA – higher activity foot, LA – lower activity foot.

DISCUSSION

Our hypothesis was not supported given the significant changes in both MOS_{AP} and MOS_{ML} across visits that were greater on average for HA. The changes seen however resulted in a more symmetrical MOS_{ML}, which may suggest reduced favoring of the sound limb, and an increased MOS_{AP}, possibly indicative of a greater balance confidence. Of clinical relevance, at the initial fitting only the LA foot had significant interlimb differences for MOS_{AP}. Furthermore, at the 3 week period, in contrast to the HA foot, the LA foot showed asymmetries in both directions.

CONCLUSION

Dynamic balance, indicated by MOS_{ML} and MOS_{AP}, improved over a 3 week adaptation period on a new prosthetic limb of the individual's prescribed Medicare functional classification level.

CLINICAL APPLICATIONS

MOS_{AP} may have value as an assessment tool at the initial fitting to determine appropriateness of a device. MOS in both directions may be a valuable assessment tool following 3 weeks of wear time.

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Feet with multi-axial rotation units enhance gait stability over uneven terrain in people with amputation

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INTRODUCTION

Individuals with transtibial amputation face serious challenges when negotiating uneven terrain. Prosthetic foot manufactures have attempted to minimize these challenges by designing prosthetic feet that can deform and adapt to uneven terrain. Feet incorporating "multi-axial" features have been given a Medicare L-Code reflecting this ability (L-5986) and have been traditionally prescribed to individuals expected to negotiate uneven environments. However, prosthetic reimbursement is changing and third-party payers are now asking for evidence to justify these features (Levinson, 2011). There is currently NO evidence that links multi-axial prosthetic ankle stiffness to gait stability. This lack of evidence could be used by third-party payers to deny reimbursement.

The purpose of this study was to define the effect of prosthetic multi-axial stiffness on gait stability in people with uni-lateral transtibial amputation. Study results should strengthen the evidence-base of prosthetic/rehabilitation interventions.

METHOD

Subjects: Eleven participants with uni-lateral transtibial amputation secondary to trauma (93.2 ± 23 kg, 1.82 ± 0.13 m, 40.0 ± 14.0 yrs) have completed this IRB approved study.

Apparatus: The uneven terrain (Figure 1) consisted of a 7.3 x 0.8m walkway with 80 x 25 x 20 cm blocks specifically placed in a rotating pattern (0˚, 45˚, 90˚, and 135˚). The center of each block was spaced 200 cm apart from each other. A 1 cm thick rubber mat was placed over the uneven walkway reducing visual feedback while making the floor appear even.

Procedures: Participants walked ten times over even and uneven terrain to a metronome (108 bpm). The uneven terrain consisted of a 7.3 x 0.8m walkway with 80 x 25 x 20 cm blocks specifically placed in a rotating pattern. A mat was placed over the uneven walkway reducing visual feedback. A full-body marker set (Vicon PlugInGait) in conjunction with an eight camera motion capture system (Vicon Motion Systems, Oxford, UK) recorded limb kinematics. The participant's regular prosthesis and an Endolite Multi-flex foot with four different ankle unit stiffnesses (soft, medium, firm, and locked out) were tested in random order. This foot was used because it allowed for easy manipulation of multi-axial stiffness, and it only uses the L5986 code (Levinson, 2011). A certified prosthetist performed all prosthetic modifications.

Data Analysis: Matlab 2013b was used to calculate whole body center of mass based on a 14 limb-segment model (De Leva, 1996) and the range of angular momentum about the coronal plane when the amputated limb was in stance (Herr & Popovic, 2008). Angular momentum was normalized to the participant's mass, velocity, and height. A two factor Repeated Measures ANOVA (terrain x ankle stiffness) with Bonferroni post-hoc tested statistical significance ($p < .05$).

RESULTS

There was a significant effect of terrain, and ankle stiffness for the range of whole body angular momentum in both the sagittal and coronal planes. A decrease in the range of whole body angular momentum means an increase in gait stability. The locked ankle condition was significantly destabilizing in both terrains and while ankle stiffness had a larger effect on uneven terrain than even terrain (Figure 1).

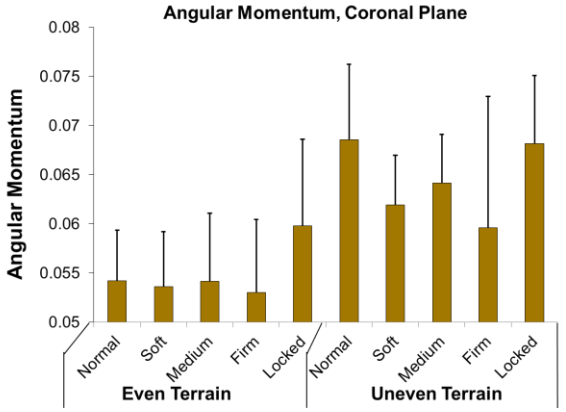

Figure 1. The range of whole body angular momentum across the feet tested and over the different terrains in the coronal plane shows feet with multiaxial features minimized angular momentum (maximized gait stability) over the locked condition in both even and uneven terrains.

DISCUSSION & CONCLUSION

Prosthetic feet with multi-axial features significantly increased gait stability over uneven terrain indicating scientific evidence supporting the use of feet utilizing the L5986 code in clinical practice.

CLINICAL APPLICATIONS

Prosthetic designs that incorporate multi-axial foot units provide a measureable benefit by enhancing gait stability and will benefit those with amputation that need to negotiate uneven terrain.

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ACKNOWLEDGEMENT

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Strategies to adapt speed differ depending on self-rated ambulatory function

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INTRODUCTION

The ability to easily respond to changing task and environmental constraints is a necessity for community ambulators. Everyday life frequently demands changes in walking speed. In able-bodied individuals a combination of increases in step length and step frequency, largely symmetrical across limbs, can be seen when an increase in speed is required (Oberg, 1993). In individuals with an amputation, the strategy adopted may depend on the individual's ability to effectively utilize their prosthesis, and their dependency on the sound limb. Such ability may be reflected in the person's self-awareness of their ambulatory function.

The aim of this study was to determine how individuals that perceived themselves to have greater ambulatory function adapt their strides bilaterally when walking at different speeds. It was hypothesized that individuals with greater self-reported ambulatory function would utilize changes in both the prosthetic and sound limbs to accomplish changes in walking speed whereas those of less self-reported ambulatory function would rely on changes within the sound limb.

METHOD

Subjects: 19 individuals with a transtibial amputation (54.3 (13.5) yrs; 1.78 (0.07) m; 98.6 (21.7) kg).

Procedures: Participants completed the Prosthesis Evaluation Questionnaire (PEQ) (Legro, 1998) based on the 4 weeks prior to the assessment. For gait measures, participants walked for 3 minutes on a treadmill at a self-selected pace and at speeds 20% slower and 20% faster. Step lengths and step times from 30 strides were extracted for analysis.

Data Analysis: Participants were ranked according to their scores in the ambulation scale of the PEQ and the top and bottom quartiles separated to form higher ability (HA) (n=5) and lower ability (LA) (n=5) groups. Within each group, sound and prosthetic step lengths and frequencies were compared across speeds using paired t-tests (α=0.05).

RESULTS

For HA step lengths and frequencies changed consistently on both sound and prosthetic sides for all speed changes (Figure 1). In contrast, the LA group showed no significant difference in sound (p=0.12) or prosthetic (p=0.13) step frequencies on increasing speed, or in the prosthetic step frequency (p=0.08) and sound step length (p=0.08) on decreasing speed (Figure 1).

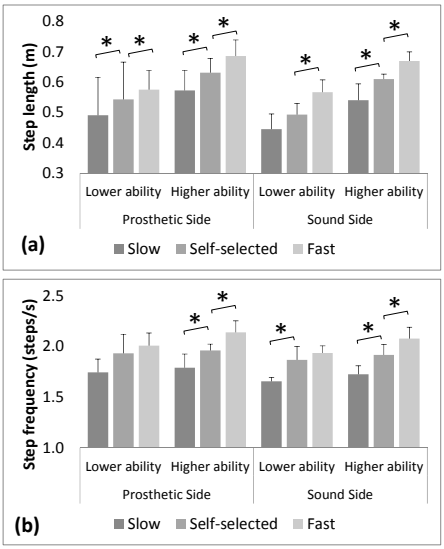

Figure 1. Stride characteristics at three speeds by perceived ambulatory ability. (a) step length, (b) step frequency (*p≤0.05)

DISCUSSION

HA and LA responded differently when required to alter their walking speed. HA consistently adapted their step length and frequency on both sound and prosthetic sides. In contrast, LA tended towards favoring their sound side to modulate speed changes. Furthermore, changes in speed for the LA individuals was accomplished more through changes in step length rather than frequency.

CONCLUSION

Our results suggest that individuals that feel they are better ambulators do in fact respond to changes in a gait task more symmetrically rather than with increased reliance upon the sound side.

CLINICAL APPLICATIONS

Patients that feel they are better ambulators do actually have measurable objective differences in gait expanding beyond self-perception.

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FPTH14

Partial Hand Externally-Powered Outcomes

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INTRODUCTION

Epidemiological data estimates that **90%** of the 20,000 new cases of upper limb loss or deficiency each year occur at, or distal to, the wrist joint (Dillingham, Pezzin, & MacKenzie, 2002). This is mirrored in the military population where **87%** of upper limb amputations occurring in all active and reserve service members from 2000-2011 were distal to the wrist joint (Armed Forces, 2012). Similarly, in the workplace **94%** of all non-fatal amputations involve the fingers (Brown, 2003). While the shoulder, elbow and wrist are critical to putting the upper limb in the proper position to engage with an object, it is the hand that typically completes complex and multidimensional tasks. This research explores how using an externally-powered partial hand prosthesis contributes to the completion of functional tasks.

METHOD

Subjects: Fifteen individuals (12 male, 3 female) being fit with either a 4-digit or 5-digit i-limb digit partial hand prosthesis were asked to participate in the study. Participants ranged in age from 26-58 with an average age of 42.

Apparatus: The Patient-Specific Functional Scale was used to identify individualized goals and have the users rank their current level of performance. The Southampton Hand Assessment Procedure was used to objectively evaluate function with and without the prosthesis.

Procedures: During one-week condensed fittings, participants and their local prosthetists consented to engage in the study. Therapists at the fitting facility conducted all outcome measures prior to fitting and post-fitting. Individuals received 10-15 hours of therapy with their prosthesis prior to post-fitting testing.

Data Analysis: Data was analyzed and compared to baseline according to clinically significant findings as defined by the outcome measure.

RESULTS

While all goals identified on the PSFS were individualized to the user, similarities were found among subjects. PSFS scores range 0-10 with 0 being unable to perform and 10 being able to perform at same level as pre-amputation. Results are significant for the minimum detectable change score required for the PSFS.

SHAP scores demonstrated significant improvement for all users. Not surprisingly, a more significant change was shown for those fit with a 5-digit system in comparison to those being fit with a 4-digit system.

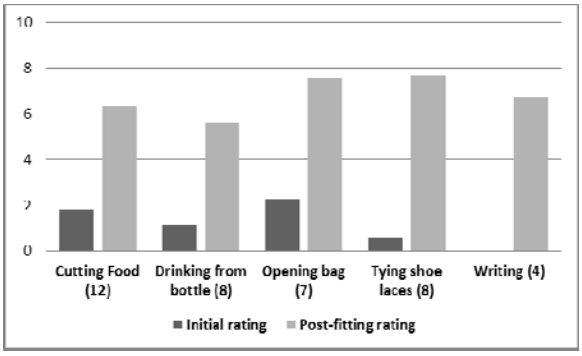

Figure 1. PSFS results. Number in paratheses represents number of individuals identifying goal.

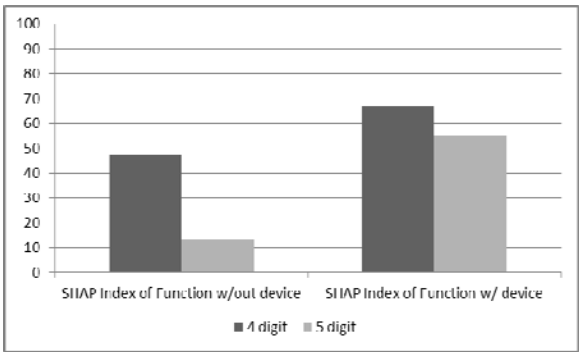

Figure 2. SHAP results with and without prosthesis. Score 0-100 with 100 being equivalent to normal hand function.

DISCUSSION

Results demonstrate the significant functional improvements that can be obtained for individuals with partial hand limb loss and deficiency.

CONCLUSION

These findings should encourage clinicians and payers on the benefit of partial hand prostheses.

CLINICAL APPLICATIONS

Individuals with partial hand limb loss or deficiency should be evaluated and appropriate prosthetic intervention recommended based on individual goals and current level of function.

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Partial Hand Amputation: A review of outcome measure data to support a patient-centered approach to successful fitting of new technologies

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INTRODUCTION

Research has shown that individuals' expectations of their upper limb (UL) prostheses play a role in prosthetic acceptance or rejection (Biddiss & Chau, 2007). We hypothesized that if both a patient and the prosthetic care team are knowledgeable in the psychosocial challenges specific to this patient population and the spectrum of available prosthetic options suitable to the patient's unique situation, the alignment of patient expectations and prosthetic rehabilitation solutions will result in positive overall acceptance and functional outcomes.

METHOD

A convenience sampling of patients with varying levels of partial hand (PH) amputation participated in a thorough evaluation during which Advanced Arm Dynamics (AAD) UL prosthetic specialists provided education regarding suitable prosthetic options for their specific situation. Each patient made an informed prosthetic solution decision and participated in an expedited fitting that included an extensive prosthetic therapy training protocol with the goal of achieving the highest possible level of functional independence with the prosthesis. All training was performed by a physical or occupational therapist in collaboration with the treating prosthetist, who made prosthetic design modifications as needed to enhance subject capabilities for task performance.

A battery of outcome measures was used to assess patients' psychological well-being at intake and their satisfaction with their prostheses and self-perceived disability at different phases of their care. This battery included: a psychological screening tool that was completed by 192 patients (65.1% male, age range 17.5 to 82.4, 45.3% PH amputation); AAD standard of care quality assurance surveys administered at intake regarding prior care (n=25), at post-definitive fitting (n=32), and six to nine months after (n=23); the Trinity Amputation and Prosthetic Experience Scales – Revised (TAPES–R) (n=17); and the Disabilities of Arm, Shoulder, and Hand (DASH) (n=29).

RESULTS

Psychological Wellness: Prior to initiation of prosthetic fitting, 59% of individuals in the PH group screened positive for depression, 29% screened positive for PTSD, and 53% reported experiencing pain.

Satisfaction: Responses to AAD survey items are shown in Table 1. Patient satisfaction was rated on a Likert scale where 1 indicated "Dissatisfied" and 5 indicated "Satisfied." Additionally, subjects reported 7.94 out of a maximum 10 overall satisfaction score on the TAPES-R.

Perceived Disability: Preliminary calculations of DASH scores of four subjects showed that scores decreased in all but one subject after fitting.

	Prior Care	Post Definitive	6 to 9 months Post Definitive
Prosthesis	2.04	4.43	4.09
Prosthesis meeting expectations	1.80	4.28	4.39
Prosthesis comfort	2.68	4.4	4.61
Team's ability to optimize fit	2.56	4.63	4.78
Team's ability to optimize function	2.04	4.75	4.83
Instruction given to operate prosthesis	2.96	4.81	4.91
Appearance of prosthesis	2.28	4.28	4.57
Understanding of how to operate prosthesis	*	4.62	4.48
Care & attention provided by prosthetic team	2.8	4.81	5.00

* Question was not included in Prior Care survey

Table 1. Patient satisfaction with prosthetic care.

DISCUSSION

Psychological Wellness: Individuals with PH amputations are more likely than individuals in the general population to screen positive for depression and PTSD. Furthermore, about 50% screen positive for pain, which may worsen depression symptoms.

Satisfaction: Compared to previous prosthetic care experiences, patients are more satisfied with the outcome following a thorough evaluation during which education is provided on all appropriate prosthetic options and a care plan that included ongoing collaborative prosthetic and therapeutic support.

Perceived Disability: DASH scores showed a trend of subjects perceiving themselves to be less disabled after prosthetic fitting.

CONCLUSION

Subjects reported higher satisfaction following a thorough prosthetic evaluation and collaborative, specialized prosthetic fitting with therapeutic intervention. Notably, higher satisfaction with the prosthesis meeting their expectations was reported.

CLINICAL APPLICATIONS

Psychological screening is indicated with this patient population to identify potential challenges to prosthetic rehabilitation success. Results from prior care may not be indicative of potential for satisfaction with prosthetic intervention and rehabilitation based on thorough evaluation, educated discussion of prosthetic options and comprehensive specialized training with patient-selected option. Overall patient satisfaction is influenced by the alignment of prosthetic function with patient expectations.

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A COMPARISON OF DIRECT AND PATTERN RECOGNITION CONTROL IN TRANSHUMERAL TMR SUBJECTS

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INTRODUCTION

Following the Targeted Muscle Reinnervation (TMR) procedure, an individual with a transhumeral amputation is able to control elbow and hand functions of a myoelectric prosthetic arm simultaneously. However, obtaining isolated electromyographic (EMG) signals for each of these functions can be difficult using traditional control methods (direct control). Pattern recognition algorithms decode EMG signals produced when a muscle contracts, and can be trained to recognize and distinguish a person's distinct muscle patterns (Kuiken, 2009).

The purpose of this study was to compare an individual's ability to control a commercial arm system using ether direct or pattern recognition control in a home trial.

METHOD

Subjects: Eight subjects with transhumeral amputation who had previously undergone TMR were recruited for the study. All subjects were male and had a medium to long residual limb.

Apparatus: Outcomes included the Box and Blocks test, the Jebsen Hand Function test, the Southampton Hand Assessment Procedure (SHAP), and the Clothespin Relocation Task. A custom survey was also administered.

Procedures: Subjects were fit in random order with direct or pattern recognition control of a Boston Digital Arm system, a Motion Control wrist rotator, and a terminal device. Subjects could choose between an Otto Bock Hand or Greifer, or a Motion Control ETD. During the direct control phase, subjects used their intact biceps and triceps to control the elbow and two TMR sites to control the hand/wrist. Subjects used each control method at home for a minimum of 6 weeks. Outcomes were administered pre- and post-home trial.

Data Analysis: An analysis of variance was performed using a general linear model with each subject as a random factor, control type, and pre/post testing as fixed factors for each outcome measure.

RESULTS

No statistical differences were noted in the results of the Jebsen or the Box and Blocks test. However, there was a significant difference in SHAP scores, with the pattern recognition control system performing statistically better ($p=0.024$) (Fig. 1). Also, during the Clothespin Relocation Task, subjects were able to move the three pins from the horizontal bar to the vertical bar faster with pattern recognition compared to direct control ($p=0.009$) (Fig.2).

DISCUSSION

Seven out of eight subjects preferred pattern recognition over the direct control configuration. The subject who preferred direct control stated that it was simpler and he frequently had confusion between the hand and the wrist movements when using pattern recognition control. The other subjects all noted that with pattern recognition, they no longer had to switch between the hand and wrist. Future work will investigate the ability of subjects with TMR who use pattern recognition to control additional degrees of freedom, including a wrist flexor and multi-articulating hand.

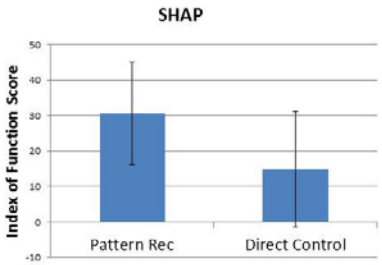

Fig 1. Comparison of SHAP test results between direct and pattern recognition control.

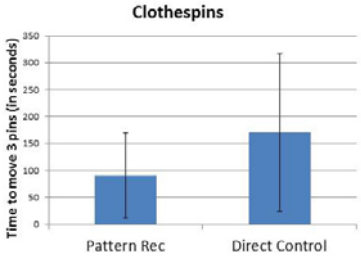

Fig 2. Direct versus pattern recognition control during the Clothespin Relocation Task.

CONCLUSION

When using pattern recognition control, subjects with transhumeral amputation who received TMR could operate their myoelectric prosthesis better when compared to using direct control.

CLINICAL APPLICATIONS

Based on the improved functional testing and subject preference, pattern recognition is a viable clinical option for transhumeral TMR patients. Future studies should include subjects with other levels of amputation.

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MICRO-PROCESSOR CONTROLLED KNEE-ANKLE-FOOT ORTHOSIS (C-BRACE) VS. STANCE-CONTROL KNEE-ANKLE-FOOT ORTHOSIS (SCO) AND CONVENTIONAL KNEE-ANKLE-FOOT ORTHOSIS (KAFO): FUNCTIONAL OUTCOMES IN INDIVIDUALS WITH LOWER EXTREMITY IMPAIRMENTS DUE TO NEUROLOGIC OR NEUROMUSCULAR DISEASE, ORTHOPEDIC DISEASE OR TRAUMA

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INTRODUCTION

A KAFO that provides mechanical support while allowing greater control in swing and stance phases of gait may increase the user's ability to walk with decreased metabolic cost and allow improved functional mobility and participation in functional activities. The Micro-processor control (C-Brace) applied to the KAFO could allow for more control during the swing and stance allowing for independence in walking on uneven surfaces, stair climbing, and self-correction during tripping[1,2]. The Aim of the study was to evaluate the potential of the C-Brace to improve the functional mobility and quality of life in individuals with lower extremity impairments as compared to the SCO and conventional KAFO.

METHOD

Subjects: 12 individuals using a locked KAFO were randomized to either SCO or C-Brace.

Procedures: following an acclimation period of one month, participants were evaluated on device use in their home for another month. Following which, participants crossed-over to the other device group (SCO or C-Brace) and received a month of acclimation followed by home trail. Outcome measures included no. of times specific ADLs were performed at home (stair climbing, walking, etc.,), metabolic cost during ADLs, device use at home and in the community, QOL. Advanced wearable sensors, GPS tracking, machine learning techniques were applied to quantify devices use at home.

Data Analysis: each participant acted as their own control. A two-way repeated measures ANOVA was used with time and device as factors to compare between and within groups.

RESULTS:

Initial results indicate that c-brace increases the number of times adls are performed such as stair climbing at home and in the community compared to the sco or kafo. In addition the metabolic costs performing the adls were lower in the C-brace usage time. In addition, the community mobility and social interaction measured using gps tracking was significantly higher in the c-brace users compared to sco or kafo.

DISCUSSION

Appropriate patient selection, acclimation, systematic and customized fitting of the C-Brace seems follow participants to perform ADLs at a higher rate but also perform large set of different ADLs compared to their predicate device. In addition, a lot of these ADLs are performed at different settings further improving overall quality of life.

CONCLUSION

Micro-processor controlled KAFO's providing advanced stance and swing control could significantly improve ever day mobility, functional activities, and quality of life in KAFO users.

CLINICAL APPLICATIONS

Advanced microprocessor controlled KAFOs even though more expensive than traditional devices does provide a much higher quality of life in terms of home and community mobility and social interaction. This gain in the long run will balance cost benefit ratio and help with the question of health care economics also.

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A new approach to orthotic treatment of knee osteoarthritis using an ankle-foot orthosis

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INTRODUCTION

Conservative treatment options of knee osteoarthritis (OA) include knee unloader braces that, according to a recent systematic review of clinical trials, result in moderate improvements in pain and function [1]. However, it also found that knee brace use is often discontinued due to constraining or poor fit, slipping, and skin irritations [1]. Therefore, an ankle-foot orthosis (AFO, Agilium Freestep) was developed to use the ground reaction force (GRF) in the frontal plane to unload the medial or lateral compartment of the knee without the adverse effects of a knee brace. The present study investigated the biomechanical effects of Agilium Freestep in the gait lab and the clinical effectiveness over 12 months.

METHOD

For the biomechanical study, 12 patients with medial knee OA (mean age 64.3±11.8 y) were subjected to instrumented gait analysis while walking with and without the Agilium Freestep AFO. For the clinical part of the study, 25 patients with symptomatic knee OA (mean age 60.5±11.7 y, 33% grade 1, 55% grade 2,12% grade 3 after Kellgren & Lawrence, 78% had prior treatment with a knee sleeve or knee brace) were enrolled. After a baseline assessment of the Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) and a visual analog scale (VAS) rating of knee pain, patients were fitted with Agilium Freestep and underwent follow-up assessments after 3, 6, 9, and 12 months. Statistical analyses were conducted using the Student´s t-test with a power of 80%.

RESULTS

In the biomechanical study, Agilium Freestep was found to shift the center of pressure (CoP) under the foot 7-10 mm lateral. In addition, it locks the subtalar joint and employs a calf upright to ensure proper force transmission to the knee joint. As a result, the lever arm of the GRF and thus the external knee adduction moment acting on the medial compartment of the knee was significantly reduced by 14% ($p \leq .01$). In the clinical study, the WOMAC composite score improved significantly from 40.9±13.4 (baseline) to 25.1±22.3 (3-m FU; $p=.03$), 20.8±17.3 (6-m FU; $p<.0001$), 20.2±20.1 (9-m FU; $p<.0001$) and 16.6±23.3 (12-m FU; $p<.0001$). The three WOMAC subscores for pain, stiffness, and physical function also improved significantly at all follow-ups compared to baseline. The VAS knee pain rating showed improvements at all follow-ups, but attained statistical significance only after 6 and 12 months. Compliance was very high with only 2 patients discontinuing use for reasons unrelated to the orthosis.

DISCUSSION

This study suggests that the biomechanical effects and clinical effectiveness of the Agilium Freestep AFO in mild to moderate knee OA have the same magnitude as those known from biomechanical and clinical trials with knee unloader braces [1, 2]. However, long-term patient acceptance of orthosis use might be improved by the AFO.

CONCLUSION

The Agilium Freestep AFO appears to be a promising orthotic treatment of knee OA with similar biomechanical and clinical effects as knee unloaders but improved long-term patient compliance.

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DISCLOSURE

Andreas Kannenberg and Thomas Schmalz are full-time employees of Otto Bock HealthCare. Hartmut Stinus received a research grant from Ottobock to conduct the clinical study.

Training Outcomes from the C-Brace® Retrospective Registry

Russ Lundstrom, MS, Alicia Drain, BS, Andreas Kannenberg, MD, PhD
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INTRODUCTION

The C-Brace Orthotronic Mobility System is a microprocessor-controlled Stance and Swing Controlled Orthosis (SSCO) developed to overcome the limitations of KAFOs that do not offer damped knee flexion during weight-bearing or dynamic swing control. A retrospective registry was designed: (1) to gather safety and effectiveness data from patients that have been fitted with a C-Brace (2) to discover what assessments are routinely performed at clinics as a part of evaluating C-Brace patients. Data on the training and training outcomes based on the chart reviews are presented to characterize C-Brace training which was used as a guide in the development of the C-Brace Prospective Registry.

METHODS

Case Report Forms (CRFs) were developed to collect data for a variety of outcome measures based on discussion with prospective sites. Planned outcome measures at Hanger included the Timed Up and Go (TUG), Fast Walking Speed (FWS), and Berg Balance Scale (BBS), an Activity of Daily Living Questionnaire (ADLQ) and the Activities-specific Balance Confidence (ABC) Scale. IRB approval for the retrospective chart review and waiver of informed consent was obtained for each participating investigator. Baseline data was collected for outcome measures using a previous orthosis or no orthosis if subjects were not using an orthosis. A training CRF was developed to collect information on training and training outcomes focused on key functions of C-Brace (e.g. donning/doffing, getting up from a seated position, sitting down in a chair loading both legs, descending ramps step-over-step, descending stairs step-over-step and resting while standing).

RESULTS

Data was collected from 19 subjects having been fitted with a C-Brace at 14 clinics. Subjects were 5 female/14 male with an estimated mean age of 49.7 years and mean weight of 204 (125-272) lbs. 10 subjects were fitted for the left leg, 8 for the right, and 1 for bilateral fitting. The data collected for outcome measures represented a mean follow-up duration after C-Brace fitting of 6.4 (0-27.8) months.

Nine (9) subjects had documented results from their training sessions in the clinic charts. The training duration from first to final training date was available for 6 subjects with an average of 39.2 (17-64) days. The number of training sessions was noted for 5 subjects with an average of 5.2 (3 to 6) sessions.

All 9 subjects were able to don/doff the C-Brace; for 5 it was noted that they could do so independently. All 9 subjects could get up from a seated position; for 5 it was noted that they could do so independently. All 9 subjects could descend both stairs and ramps with a step-over-step pattern; for 2 it was noted that they could descend ramps without using a handrail, and for 3 it was noted that they could descent stairs without using a handrail.

12 subjects in the study had some outcome measures at both baseline and follow up. While 10 of 12 subjects had clinically meaningful improvements in at least 1 outcome measure, only 4 of these also had documentation regarding training, so the impact of training on outcomes could not be assessed.

DISCUSSION

For some clinics, off-site training resulted in documentation being unavailable to this registry. For this reason, our results cannot be used to estimate the proportion of C-Brace patients that are getting training. However, of those that had training documentation, the number of sessions is consistent with Ottobock recommendations for training and physical therapy based on established YouTube videos.

Training outcomes were consistent with those published by Schmalz et al [Ref 1], in which all subjects were able to demonstrate a reciprocal gait ambulating down stairs and ramps. Schmalz reported that none of the subjects were able to use reciprocal gait pattern down stairs with their previous orthoses; such data for previous orthoses was not available in this registry. While it was reported in this registry that 3 of the 9 subjects were able to walk down stairs without the use of the handrail, it should be noted that the C-Brace Instructions for Use includes a caution that the handrail should always be used when walking down stairs with the C-Brace.

CONCLUSION

Results from this retrospective registry revealed that all C-Brace subjects with documented training were able to demonstrate the ability to utilize the key features of the C-Brace, including the ability to walk down stairs and ramps with reciprocal gait. Future research is warranted to determine the impact of training on clinical outcomes.

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ACKNOWLEDGEMENTS

Funded by Ottobock. Special thanks to Deanna J. Fish, MS, CPO, and Dale Berry, CP, Hanger Clinic, for input and support for the C-Brace Retrospective Registry.

Effectiveness Results from the C-Brace® Retrospective Registry

Russ Lundstrom, MS, Alicia Drain, BS, Andreas Kannenberg, MD, PhD
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INTRODUCTION

The C-Brace Orthotronic Mobility System is a microprocessor-controlled Stance and Swing Controlled Orthosis (SSCO) developed to overcome the limitations of KAFOs that do not offer damped knee flexion during weight-bearing or dynamic swing control. A retrospective registry was designed: (1) to gather safety and effectiveness data from patients that have been fitted with a C-Brace (2) to discover what assessments are routinely performed at clinics as a part of evaluating C-Brace patients. Effectiveness results from the chart reviews are presented to characterize potential patient benefits and to guide in the selection of measures to be used in the C-Brace Prospective Registry.

METHODS

Case Report Forms were developed to collect data for a variety of outcome measures based on discussion with prospective sites. Planned outcome measures at Hanger included the Timed Up and Go (TUG), Fast Walking Speed (FWS), and Berg Balance Scale (BBS), an Activity of Daily Living Questionnaire (ADLQ) and the Activities-specific Balance Confidence (ABC) Scale. IRB approval for the retrospective chart review and waiver of informed consent was obtained for each participating investigator. Baseline data was collected for outcome measures using a previous orthosis or no orthosis if subjects were not using an orthosis. Patient questionnaires were also mailed to patients by the Hanger clinics and completed questions made available for additional data collection to provide long-term, patient-reported outcomes.

RESULTS

Data was collected from 19 subjects having been fitted with a C-Brace at 14 clinics. Subjects were 5 female/14 male with an estimated mean age of 49.7 years and mean weight of 204 (125-272) lbs. 10 subjects were fitted for the left leg, 8 for the right, and 1 for bilateral fitting. The data collected for outcome measures represented a mean follow-up duration after C-Brace fitting of 6.4 (0-27.8) months.

The baseline (B/L) and change (Chg) scores for each of four outcome measures are summarized in the table below.

Outcome	FWS m/s	BBS score	ADLQ (Mobility) score	ABC %
n	7	7	10	10
Cut-off	0.1	4	1	15%
Avg B/L	1.1 ± 0.50	44.9 ± 7.5	1.2 ± 1.13	37 ± 24%
Avg Chg	0.22 ± 0.26	1.57 ± 0.98	1.4 ± 1.38	15 ± 23%
Med F/U	3 mos	3 mos	15 mos	15 mos

Cut-off scores were established for each outcome measure to determine the level of change from baseline that would be considered clinically meaningful. Clinically meaningful improvements were observed based on the mean change scores for FWS, ADLQ Mobility subscale and ABC. TUG results are not presented, since only 4 subjects had data at both baseline and follow up.

DISCUSSION

Clinically meaningful changes compared to baseline for were observed in 10 of 12 subjects (83%) that had efficacy data at both baseline and follow-up. 5 of 7 (71%) of subjects had a clinically meaningful change in FWS. One had a clinically meaningful decline (>0.1 m/s slower), but this subject was already walking at 1.74 m/s at the time of C-Brace fitting. No information on gait quality in this subject was available.

Subject	FWS	BBS	ADLQ (Mob)	ABC	FU (mo)	👍?
0204					1	✓
0208					1/12*	✓
0212					24	✓
0213					18	✓
0214					12	
0216					6	✓
0217					18	✓
0220					30	✓
0222					24	✓
0224					6	✓
0301					3	
0302					3	✓

= clinically meaningful improvement
= clinically meaningful decline, ☐ = no change
= no data
**FWS & BBS assessed at 1 mo; ADLQ &ABC at 12 mos.*

CONCLUSION

Results from this retrospective registry revealed that the majority of C-Brace subjects have demonstrated clinically meaningful improvements in outcome measures. FWS and ABC, in particular, appear to be sensitive outcome measures in the majority of subjects with implications for use in the planned prospective registry. The immediate orthotic effect was mixed in patients, which highlights the importance of training and accommodation before clinically meaningful improvements can be observed.

ACKNOWLEDGEMENTS

Funded by Ottobock. Special thanks to Deanna J. Fish, MS, CPO, and Dale Berry, CP, Hanger Clinic, for input and support for the C-Brace Retrospective Registry.

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Use of Contact Detection Reflex to Improve Fragile Item Grasp in Myoelectric Prostheses: A Novel Technology

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Stanford University[1], Berke Prosthetics[2], SynTouch LLC[3], University of Southern California[4]

INTRODUCTION

While myoelectric prostheses have been available for many years, widespread use has been limited by issues of rejection and narrowed use patterns. One limitation of myoelectric hand use is the cognitive burden required for difficult tasks like grasping fragile items, which is postulated to lead to limited use, passive use, or rejection. The purpose of this research is to determine if a contact detection reflex that is inspired by a biological reflex can improve the use of myoelectric prostheses for fragile item grasp. This has the potential to decrease cognitive load and improve long-term use and function.

METHODS

Subjects were recruited from the research area using IRB protocol. 4 subjects (2 male and 2 female) meeting the criteria agreed to participate. Each subject had unilateral limb loss/failure of formation of the upper extremity below the elbow and a history of sustained myoelectric prosthesis use (3-27 years). All subjects used an Ottobock proportional control myoelectric hand optimized by his or her personal prosthetist and were comfortable using this device throughout the testing process.

Each subject was asked to accomplish three separate tasks as quickly as possible: grasp and move ten 'Ritz' crackers to a cup, grasp and move ten hollowed eggshells from one tray to another, and lift and move ten full soda cans. In all tasks, this distance moved was two feet and objects that were dropped or broken did not count towards the total. The tasks were performed under three testing conditions: using the sound side limb (SS), with the subject's personal myoelectric prosthesis (PP), and with a modified prosthetic terminal device incorporating a contact detection reflex (CD). Time was recorded during each task and five timed trials of each condition were performed.

The modified terminal device (CD) is a standard VariPlus Speed hand (Ottobock) altered by replacing the fingers and thumb with compliant NumaTac contact sensors (SynTouch) and a microprocessor that altered the hand's behaviour by reducing EMG signal gain after contact to facilitate low force grips. Each subject was given a short questionnaire before and after testing to obtain self-reported outcome data. Data was analyzed using a repeated measures ANOVA and a Holm t-test to compare both devices with sound side performance and with one another.

RESULTS

Results for all subjects on the two tasks with fragile items (crackers and eggs) showed that time with the prosthesis with contact detection was significantly improved compared to the subjects' personal prostheses (CD vs PP). Additionally, on the cracker-grasping task, the modified prosthesis was *not* statistically worse than the sound side performance (CD vs SS). On the rigid grasping task (soda), both prostheses had similar performance (PP vs CD).

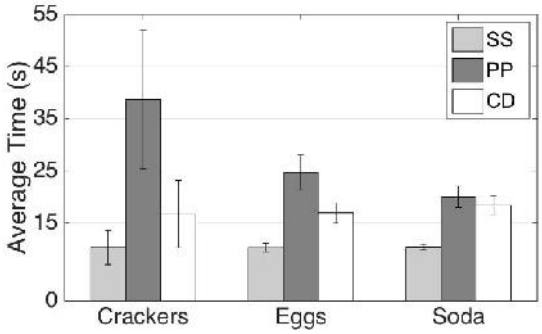

Figure 1. Experiment Results.

DISCUSSION

The contact detection strategy employed made fragile grasping with a prosthesis significantly faster and easier, despite little training. Timed scores indicate improvement in the fragile item domains with no change in time for heavier item grasp. With additional experience, it is anticipated that the modified device would facilitate increased daily use and improved function.

CLINICAL APPLICATIONS

Analysis of self-reported outcome data demonstrated that subjects avoid fragile grasping tasks with their personal prosthesis despite rating it as an important activity. Every subject stated preference for the experimental prosthesis on ease of use and confidence in grasping fragile objects, as well as requiring less concentration to use. All subjects preferred the experimental prosthesis to their current device and reported that it would increase both wear time and hand usage.

CONCLUSION

The combination of contact sensing and a contact detection reflex, resulting in quick and responsive movement before grasping and sensitive and intuitive force control after grasping, significantly improved ease and efficiency of fragile grasping tasks with no adverse effects on rigid item grasping. Future research will focus on understanding the effect of this technology on cognitive load and making further improvements to the NumaTac technology.

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THE EFFECT OF DIFFERENT PLACEMENT OF HEEL ROCKERS ON KINEMATICS OF LOWER LIMB JOINTS IN HEALTHY SUBJECTS

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INTRODUCTION

Rocker-sole shoes have been commonly prescribed for both healthy and pathological populations aimed at decreasing stresses on lower limbs (Long et al 2009). Typically a heel-to-toe rocker sole is rigid and rounded off at the bottom to facilitate the roll-over of the foot during gait (Hutchins et al. 2009).

An optimal design of a rocker shoe must consider both toe and heel rockers; however, most studies have focused on the toe rocker's position. Therefore, the aim of this study was to assess the effect of different placements of heel rockers on the kinematics of lower limb joints.

METHOD

Eighteen healthy female volunteers with an average age of 24 ± 4.75 years, height of 159.1 ± 3.27 cm and body mass of 54.6 ± 6.48 kg participated in this study. The participants provided written informed consent. Three pairs of rocker shoes with different of heel rocker apex positions and one pair of unaltered flat shoes were constructed. The rocker shoes were characterized by a heel-to-toe rocker sole with the toe apex positioned 63% of the foot length and angled at 25º and the heel rocker apex was angled at 15º and placed on three different positions: anterior to the medial malleolus in shoe A, on medial malleolus in shoe B and posterior to the medial malleolus in shoe C. The flat shoe (D) was unaltered (Figure 1). 3D kinematic data were recorded using 6 infrared Vicon cameras. All participants walked at self-selected speed 3 times with each shoe type while kinematic and kinetic data were recorded. Afterward, each gait cycle was divided into four distinct intervals including Initial Contact (IC), Single Limb Support (SLS), Terminal Double Stance (TDS) and Swing (SW). Finally, desired variables were computed in each interval. Statistical analyses were conducted using SPSS software.

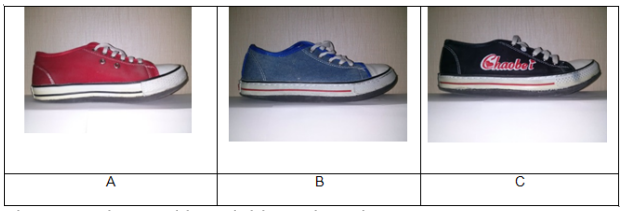

Figure 1: Shoes with variable rocker placement

RESULTS

Cadence was greater with shoe A than shoe D (P = 0.02). When walking with shoe A, stride length increased compared to the other shoe conditions (P < 0.05). Sagittal knee and hip joint motion was the same across all shoes. However, there was a significant difference between shoe B and C in ankle range of motion during IC (P = 0.04) (Table 1). During SLS, ankle ROM increased with shoe A vs. C (P = 0. 02), but decreased with shoe B and C compared to shoe D (P = 0. 04, P = 0. 01).

Shoe	IC	SLS	TDS
A	11.59 ± 5.64	**23.20 ± 8.99[b]**	30.95 ± 7.08
B	**11.38 ± 5.25[a]**	**21.30 ± 7.91[c]**	29.77 ± 6.14
C	**12.85 ± 4.73[a]**	**19.52 ± 5.13[b,d]**	29.46 ± 5.79
D	12.00 ± 4.58	**22.95 ± 7.87[c,d]**	30.11 ± 6.73

Table 1: Ankle ROM during stance. Bold superscripts indicate statistical significance.

DISCUSSION

Our analysis demonstrated that backward/forward shifting of heel rocker axis affects the ankle ROM. In agreement with previous studies that showed rocker profiles have minimal effect on kinematics and kinetics of more proximal joint of lower limb, the ROM of hip and knee joint in sagittal plane was the same between all shoes.

CONCLUSION

Variable placement of the heel rocker in a rocker-bottom shoe affects gait kinematics, even when toe placement is kept constant. The effect is most prevalent in ankle range of motion earlier in stance, and knee and hip range of motion are not affected.

CLINICAL APPLICATIONS

Although most research addresses toe rocker position, the placement of heel rocker in a rocker-bottom shoe can be manipulated to produce desired ankle range of motion.

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THE EFFECT OF WALKING IN FOOTWEAR WITH VARYING HEEL SOLE DIFFERENTIALS ON SHANK & FOOT SEGMENT KINEMATICS

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INTRODUCTION

Adults and children walk in footwear that is described as being either 'flat' or having a 'heel'. Footwear with a heel has a positive 'heel sole differential' (HSD): the difference between the height of the heel (the rearfoot height) and the thickness of the sole of the footwear at the metatarsal phalangeal joints (the forefoot height). When walking in footwear with a positive HSD the sagittal kinematics of the base of the footwear appears to mimic the kinematics of the foot in normal barefoot walking creating an 'effective foot' that is separate from the 'actual foot'. Furthermore, sagittal lower leg or shank, thigh, and trunk kinematics appear to remain unchanged. In fact, when observed by eye, walking in footwear with a positive HSD is virtually identical to walking barefoot except when very high heeled shoes are worn. These observations require description and quantification as they are an important phenomenon for both orthotic and prosthetic practice. Hence, the purpose of this study was to assess the effect of footwear with different HSDs on the sagittal shank and foot segment kinematics of walking in able-bodied persons.

METHOD

Subjects: A convenience sample of 10 nondisabled adult female volunteers experienced in walking with shoes with different HSDs were retrospectively assessed (Hansen and Childress, 2004).

Apparatus: Gait data were recorded using an eight-camera motion analysis system (Motion Analysis Corporation). Motion data were sampled at 120 Hz. A modified Helen Hayes marker set was used.

Procedures: Gait data were collected while subjects walked with no-heel, mid-heel and high-heel shoes, for at least five trials of each condition.

Data Analysis: Data were used to calculate the shank segment angle with respect to the vertical of the laboratory frame (the shank-to-vertical angle) and the actual foot segment angle with respect to the horizontal of the laboratory frame, (the foot-to-horizontal angle), as a function of the gait cycle (GC). Stride lengths were measured as well as the footwear HSD's. The degree of pitch of the footwear was calculated. A one-way multivariate analysis of variance (MANOVA) was conducted for segment kinematics and an ANOVA for stride lengths.

RESULTS

The mean HSD of the footwear were: no-heel shoes 0 ± 0 mm, mid-heel shoes 37 ± 10 mm, and high-heel shoes 71 ± 17 mm. For the three footwear conditions there was no significant difference in stride lengths ($p = 0.056$). From 0-50% GC there was also no significant difference in shank kinematics with changes in HSD, $F(6, 52) = 2.025$, $p=0.079$; Pillai's Trace = 0.993; partial eta squared = 0.189. There was however, between 0-50%GC, a significant difference in actual foot kinematics with changes in HSD, $F(6, 52) = 8.182$, $p=0.000$; Pillai's Trace = 0.971; partial eta squared = 0.486. The actual foot segment angle increased with increasing HSD and pitch.

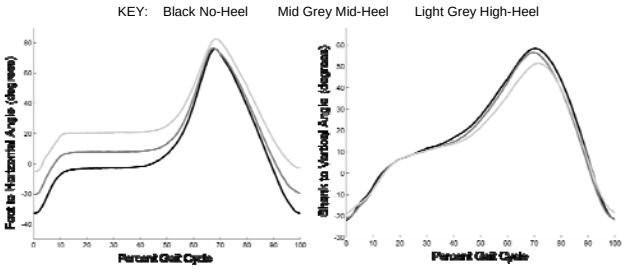

Figure 1. Actual Foot Segment and Shank Segment Kinematics

DISCUSSION

In terms of HSD, the no-heel condition was equivalent to barefoot walking. Shank kinematics during 0-50% gait cycle were similar regardless of the footwear HSD. The no-heel foot kinematics were being produced by an "effective foot" on the bottom of the heeled shoes, the actual foot shifting its angle by the degree of pitch of the footwear and the ankle joint adapting its kinematics so that shank segment kinematics remained invariant (Owen, 2010). These findings are consistent with research findings on roll-over shapes (Hansen & Childress, 2004) and ankle kinematics in footwear (Murray, 1967). Further research is needed to compare segment kinematics of the effective foot, thigh, pelvis and trunk in varying HSDs to segment kinematics when walking barefoot.

CONCLUSION

During 0-50% gait cycle stance phase shank kinematics do not change with changes in HSD. Actual foot angles do change, increasing with increasing HSD of footwear and by the angle of pitch of the footwear.

CLINICAL APPLICATIONS

Many patients will be able to walk with normal effective foot and shank kinematics when a short calf muscle or restricted ankle joint movement is present if footwear with an appropriate HSD is provided. It is also possible to incorporate these principles into other orthotic and prosthetic designs.

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MAXIMIZING FUNCTIONAL OUTCOMES UTILIZING OBJECTIVE GAIT ANALYSIS
A CASE STUDY: CHARCOT-MARIE-TOOTH ORTHOTIC TREATMENT INTERVENTIONS

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INTRODUCTION

Charcot-Marie-Tooth (CMT) is one of the most common inherited neurological disorders, affecting approximately 1 in 2,500 people in the United States. The neuropathy of CMT is a slowly degenerative process with symptoms often starting in adolescence or early adulthood and typically results in weakness of dorsiflexors, plantarflexors and the intrinsics of the feet. CMT is not considered a fatal disease and people with most forms of CMT have a normal life expectancy however they typically require physical therapy, orthotic intervention and assistive devices to maintain mobility during their lifetime[1]. Identifying maximal functional outcomes is often limited to visual gait analysis and subjective patient commentary and it can be difficult to know if an adjustment or change of design has made a difference to function. Utilizing a portable computerized gait analysis system, we are able to quantify measures of gait modify our components, designs and gait training to maximize functional outcomes of orthotic intervention.

METHODS

A single female patient with a 15 year history of CMT affecting bilateral lower extremities was tested in 3 different bilateral conditions. The custom fit dynamic carbon composite AFO designs included 1) without adjustment; 2) with increased rigidity without adjustment; 3) same rigidity as condition 2 with an adjustment to customize the orthosis for the heel height of the shoe. Temporal-spatial and pelvic motion was collected utilizing a BTS G-Walk Portable Gait Analysis System placed at the L5 vertebral level[2]. Speed, percent of double limb support, and pelvic kinematics were compared across the conditions and to normal values for women.

RESULTS

Speed and percent double limb support were closest to normal values when the patient ambulated with the orthoses that were more rigid, custom fit, customized for heel height and manufactured fully of carbon composite. Pelvic range of motion in 3 planes shows that orthotic interventions with more rigid profiles reduce pelvic motion primarily in the transverse plane.

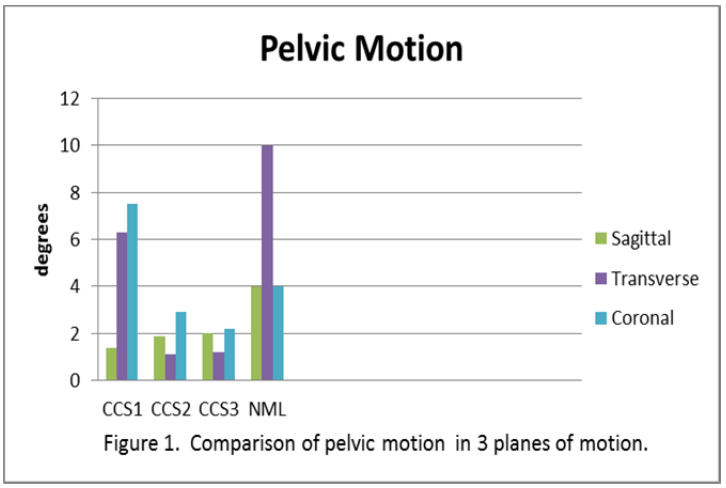

Figure 1. Comparison of pelvic motion in 3 planes of motion.

DISCUSSION

Comparing objective measured values provides guidance for providing the orthotic design with maxium functionality for the patient. Utilizing the G-Walk system functional outcomes due to changes in orthotic design and customization can be measured and documented. The orthotic intervention that provides the maximum function for this patient allowed for increased speed and decreased pelvic motion, which happened to be the more rigid design customized for heel height. By utilizing a portable computerized gait analysis system changes in gait function can be monitored over time and with changes to orthotic intervention as well as physical therapy treatments.

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DISCLOSURE

Vincent DeCataldo, BOCPO, NJ LPO is employed by Allard USA manufacturer of dynamic carbon composite AFOs.

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Thank you to Virginia Mamone and Orthopedic Motion, Inc.

Elevated vacuum socket suspension improves balance and gait performance in elderly dysvascular transtibial amputees

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INTRODUCTION

Lower-limb amputation leads to physical and functional deficits, most frequently with impairments in balance, gait and transfers (1). Poor socket suspension is an issue that frequently compromises the ability of the patient to develop confidence and walk safely with the prosthesis, especially in elderly TT amputees. Therefore, the purpose of this study was to investigate whether a vacuum assisted socket suspension system (VASS) improves the control of the prosthetic limb, stability, balance, and walking capabilities in elderly TT amputees.

METHOD

A convenience sample of 16 transtibial amputees meeting the following inclusion criteria was enrolled to this study: age 50 years or older, unilateral dysvascular TT amputation, informed consent to participate. Patients underwent the four square step test (FSST), Berg balance scale (BBS), the timed up and go test (TUG), the 6 minute walk test (6MWT) and answered the Locomotor Capabilities Index (LCI-5) and Houghton scales at baseline as well as after four weeks of use of the VASS Harmony system (Otto Bock HealthCare, Duderstadt/Germany). Statistical analysis was conducted using the Wilcoxon signed rank test with a power of 80%.

RESULTS

16 dysvascular TT amputees (14 males, 2 females) with an average age of 65.1 ± 10.1 years, 6 patients MFCL-2, 10 patients MFCL-3, completed this study. Patients highly significantly improved their balance on the BBS from 45.7 ± 6.9 to 49.1 ± 5.6 (p=.01) and in the FSST from 18.2 ± 3.8 sec to 15.0 ± 3.9 sec (p=.01) when using the VASS Harmony. Average TUG times highly significantly improved from 14.3 ± 3.3 sec to 11.6 ± 2.5 sec (p=.01). The distance walked in the 6MWT improved significantly from 288.5±59.6 m to 321.4 ± 72.8 m (p=.01). In the MFCL-3 subgroup, use of the Harmony VASS resulted in significant improvements in the Berg Balance Scale (p=.03), FSST (p=.01), TUG (p=.01), 6MWT (p=.01), and LCI-5 (p=.04). In the MFCL-2 subgroup, use of the Harmony VSS lead to significant improvements in the FSST (p=.04) and the Houghton scale (p=.04).

DISCUSSION

The results of this study suggest that the Harmony VASS supports the control of the prosthesis which in turn results in improved balance and walking performance of elderly dysvascular transtibial amputees. Subjects with MFCL-3 mobility demonstrated significant improvements in almost all outcome measures related to the risk of falling and walking capacity. Individuals with MFCL-2 mobility showed similar trends, but due to the limit sample size the differences attained significance only in the TUG indicative of the risk of falling and in the Houghton scale representing prosthesis use. The reason for these improvements is likely the improved linkage between the residual limb and the prosthetic socket that minimizes relative movements and pistoning between the residual limb and the prosthetic socket (4, 5), thus improving “proprioception” and motor control of the prosthesis.

CONCLUSION

This study has demonstrated that elevated vacuum suspension using Harmony VASS may improve safety, balance and walking performance in dysvascular TT amputees as compared to regular prosthetic sockets.

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DISCLOSURE

Andreas Kannenberg is a full-time employee of Otto Bock HealthCare LP, Austin, TX, the manufacturer of the Harmony VASS. Luis

Guirao Cano and his team received a research grant from Ottobock to conduct this study.

SOCKET FIT INDICATIONS USING ELEVATED VACUUM: A RETROSPECTIVE ANALYSIS OF CLINICAL DATA

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INTRODUCTION

Currently there is a lack of clinically relevant methods to quantify socket fit, nor is there any method to quantify changes to socket fit or the level of suspension a prothetic user is experiencing. Monitoring the sub-atmospheric pressure profile during gait may enable a clinically relevant method of assessing socket fit. Understanding Boyle's Law, which states that pressure is inversely related to volume in a closed system where temperature remains constant. Therefore any change in the sub-atmospheric vacuum pressure must be a result of movement of the residual limb within the socket.

A previous clinical investigation of transfemoral amputees found a strong linear correlation between distal displacement of the socket relative to the residual limb and changes in the elevated vacuum pressure profile (Gershutz 2010). Related work (see complimentary abstract) conducted in a controlled bench top simulation discovered a transition in interface stiffness that occurs as the vacuum pressure is increased. The purpose of this study is to retrospectively analyze the previous clinical data to determine if the transition in interface stiffness detected in the controlled bench top experiment exists in the data from the clinical setting study.

METHOD

Subjects: Five unilateral transfemoral amputees participated in the initial data collection.

Apparatus: An inductive proximity sensor was used to measure the distal displacement. The sensor was mounted to the distal end of the socket and tracked the position of a metal target adhered to the distal end of the liner wore by the subjects. The sensor was held in position by a threaded nut embedded in a PVC fitting and secured with an additional threaded nut. The prosthetic sockets incorporated the LimbLogic Vacuum System which was turned on for the elevated vacuum suspension conditions and in "Standby' mode for the suction suspension condition. The LimbLogic communicator was used to wirelessly stream negative pressure data.

Procedures: All patients were fit with a zero ply total surface bearing socket by a certified prosthetist. Subjects were asked to don the prosthetic liner and the metal target was placed on the distal end of the liner using double-sided adhesive tape. The patient was asked to don the socket and seal the interface by reflecting the liner over the brim. With the patient standing, the inductive sensor was threaded into position and the corresponding suspension treatment was applied. The patients were asked to walk in place between parallel bars for 20 seconds. Simultaneous displacement and vacuum pressure responses were collected. Tissue type was assessed by a certified prosthetist on a five point scale: soft, soft-medium, medium, medium-firm, and firm.

Data Analysis: Both the displacement and vacuum pressure response data were processed by calculating the absolute deviation, maximum minus minimum, for each step cycle. For the retrospective analysis of data, linear regression lines were fit to the lower (less than 12 inHg) and higher levels (greater than 12 inHg) of suspension respectively. The corresponding slopes were compared and a Wilcoxon Signed Rank Test used for statistical analysis.

RESULTS

The results indicate that as the vacuum pressure increases, there is a transition point where there is a significant increase in stiffness at the interface. Similar to the controlled benchtop test, the maximum stiffness achieved varied among individual subjects, suggesting differences in soft tissue compliance and the fit of the prosthesis. The patients with a firmer tissue type displayed higher pressure fluctuations than the patients with medium tissue type for a given amount of distal displacement.

DISCUSSION

Overall, the retrospective results provide additional insight than previously reported. The change in interface stiffness for each subject is aligned with clinician-based classification of tissue type and can explain in part the differences across subjects. Socket fit can also account for some of these differences. This was explored in further detail in a controlled benchtop experiment (see other abstract). The benchtop platform provided a more ethical means to investigate the effect of socket fit (potentially mal-fitting) on the sub-atmospheric pressure profile.

CONCLUSION

The study confirmed related benchtop results of a change in interface stiffness as vacuum pressure is increased. Future work is needed to quantify a clinically optimal interface stiffness to promote functional utility and maximize residual limb health.

CLINICAL APPLICATIONS

These results lead toward the development of socket fit parameters to optimize patient care by augmenting subjective feedback from patients and reliance on previous experiences by clinicians.

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SOCKET FIT INDICATIONS USING ELEVATED VACUUM: A CONTROLLED MECHANICAL ANALYSIS

Wernke, M.M., Schroeder, R.M., Nolt, L.L., Haynes, M.L, Nixon, D.M., Denune, J.A., Colvin, J.M.
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INTRODUCTION

Elevated vacuum suspension creates sub-atmospheric pressure between the prosthetic socket and the interface material. Monitoring the sub-atmospheric pressure profile during gait may enable a clinically relevant method of assessing socket fit. The underlying principle stems from Boyle's Law which states that pressure is inversely related to volume in a closed system (a sealed socket system). In other words, if there is a change in vacuum pressure, it must be the result of a change in volume between the liner and socket, and therefore there must be movement of the residual limb within the socket.

Preliminary work compared the change in sub-atmospheric pressure during level-ground gait to an inductive-based proximity sensor mounted to the distal end of the socket of 5 amputee subjects (Gershutz 2010). A strong linear correlation between a decrease in vertical displacement and a decrease in the change in vacuum pressure waveform magnitude was found; however the slope of the regression lines varied across subjects. The variance may be due to different gait styles, different tissue types and residual limb geometries, and different socket fits. The purpose of this study was to investigate the influence of socket fit, residual limb size, and socket design on the correlation between vacuum pressure fluctuation and distal displacement in a controlled environment.

METHOD

Residual Limb Models: Three residual limb models of different sizes were constructed consisting of a rigid plastic core surrounded by a compliant thermoplastic elastomer. A uniform thickness liner was cut into three sections and donned over the model (Figure 1). Removing one of the sections allowed the fit of the socket to be adjusted simulating clinically relevant socket-residual limb volume discrepancies. Two sockets with different sealing locations were fabricated for each residual limb model.

Apparatus: Leveraging the mechanical testing platform for ISO 10328 (Gershutz 2011) (Figure 1), researchers were able to control the magnitude, direction, and frequency of load application. The machine connections were modified for this test to allow tension and compression.

Procedures: A consistent sine-wave force was applied, alternating between ±30 lb. The test was performed for vacuum settings of 5, 10, 15, and 20 inHg and socket fit conditions of a normal fit, tight fit (distal liner section removed), and loose fit (middle liner section removed). Three repetitions of each trial combination were repeated totaling 864 total trials.

Data Analysis: Displacement and vacuum pressure data were processed by calculating the absolute deviation (max-min) for each force cycle.

RESULTS

The results indicate that as the vacuum pressure increases, there is a transition point where a significant increase in stiffness at the interface exists. Socket fit had a significant impact of the maximum interface stiffness as well as the magnitude of the transition in stiffness. Additionally, sealing more proximal on the socket resulted in less movement of the residual limb model within the socket compared to a distal sealing location.

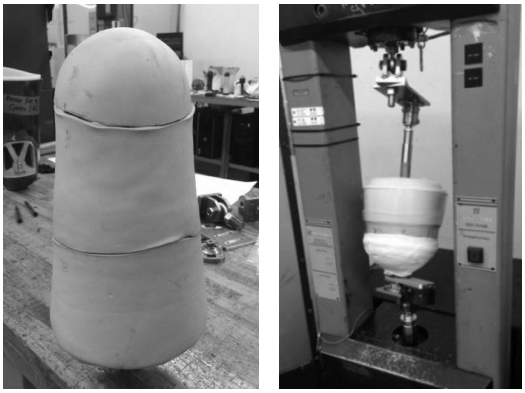

Figure 1: *Left*: Residual limb model with the divided liner. *Right:* Adaption of ISO 10328 Configuration 1.

DISCUSSION

Agglomeration of the results suggests the transition in interface stiffness occurs because increased vacuum levels decrease or eliminate (depending on socket fit) separation between the socket and limb model and any compliance at the interface is a result of thermoplastic elastomer deformation.

CONCLUSION

Application of Boyle's Law to evaluate socket fit appears to provide a clinically relevant method for clinicians. Future work can pair the method leveraged here with clinical studies to quantify limb health in order to define optimal socket fitting parameters.

CLINICAL APPLICATIONS

Leveraging this technique could provide clinicians a tool to optimize socket fit and maximize functional performance and comfort. Ultimately, this work will improve amputee care and quality of life through more quantitative analysis and documentation of socket fit.

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EFFECTS OF PROSTHETIC SOCKET SUSPENSION TYPES AND ALIGNMENT ON SOCKET INTERFACE PRESSURE AND GAIT IN TRANSTIBIAL AMPUTEES

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INTRODUCTION

Comfort and function are closely related to the socket suspension and alignment, and poor suspension and alignment is usually accompanied with discomfort and skin breakdown and/or ulceration. The object of this study is to investigate the interface pressure of gel liner socket, perception of comfort and gait in unilateral transtibial amputees when socket alignment was systematically adjusted with and without locking-pin.

METHOD

Subjects: ten unilateral transtibial amputees (age (mean±SD): 56±7 yr; body height: 1.72±.12 m; body mass: 92.5±14.2 kg) participated in the study.

Apparatus: two F-socket pressure sensors were used to register the pressure distribution around the anterior and lateral sides of the residual limb (Tekscan Inc., USA). GAITRite (CIR Systems, Inc. PA, USA) was used to obtain spatiotemporal characteristics of gait.

Procedures: F-socket sensors were placed on the residual limb covering the lateral and anterior of the limb (Figure 1). The socket alignment was systematically adjusted in both sagittal and frontal planes. In total, five socket alignments were tested including neutral, flexion, extension, adduction and abduction of 5 degrees. Participants walked cross the GAITRite mat at self-paced speed and repeated three times. The same procedure was repeated with locking pin removed. In addition, a visual analogue scale (VAS), (0– 10(most comfortable)) was collected.

Data Analysis: spatiotemporal characteristics of gait were obtained directly from GAITRite and peak pressures were identified during stance phase (Figure 2). Repeated measures ANOVA was used and the significance level was set at alpha = 0.05.

RESULTS

Socket interface pressure

Socket alignment affects the socket interface pressure distribution systematically. Particularly, suspension types play an important role. For example, the peak pressure around the fibula head is significantly higher (180 Kpa) with locking pin than that without locking pin (40 Kpa).

Gait

Participants walked at comparable speeds (.62±.21 m/s to .66±.25 m/s) and cadence (70±23 to 73±21 steps/min) across test conditions. The heel-to-heel base support (HH) peaks when the socket is set at adduction (i.e. HH =.18±.04 m). The narrowest HH is achieved when the socket is set at abduction with locking pin (.14±.05 m). The stance phase as a percentage of the complete gait cycle is significantly affected by suspension types (P=0.042). Participants were in favour of conditions with locking pin and rated socket extension and abduction as the two least comfortable conditions.

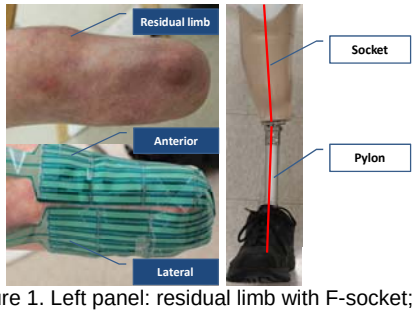

Figure 1. Left panel: residual limb with F-socket; Right panel: socket alignment adjustment.

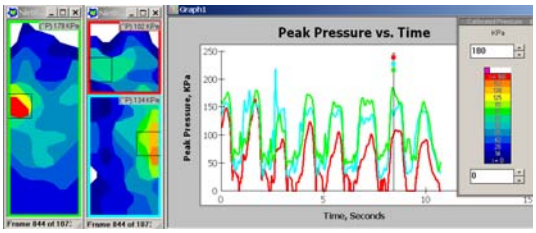

Figure 2. Example of F-socket sensor mapping and pannel segmentations.

DISCUSSION

Locking pin appears beneficial in improving suspension of the socket. Participants unanimously rated locking pin with neutral socket alignment as the best configuration. Hence it seems that the perceived performance of the socket might be more affected by the socket interface pressure distribution and socket security than the gait parameters.

CONCLUSION

Both socket alignment and suspension types affect spatiotemporal gait parameters and socket interface pressures.

CLINICAL APPLICATIONS

The outcome of this study might help us better understand the effects of suspension types and socket alignment and provide practitioners useful clinical recommendation.

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CLINICAL INVESTIGATIONS SURROUNDING A NOVEL TRANSFEMORAL SOCKET SYSTEM

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INTRODUCTION

Transfemoral amputees present many challenges for today's prosthetists, from achieving a comfortable fitting socket and interface to achieving adequate suspension during daily ambulation. Clinicians remain very interested in seeking new technologies or techniques to better treat their patients. Recent advances in socket design and technologies have led to the advent of many new socket systems to the prosthetic market. The purpose of this study is to focus on research outcomes surrounding one of these novel systems. The development of this novel socket system (NSS) was realized during a VA funded project focused on improving the fit, function, and comfort of transfemoral prosthetic sockets. The resulting system consists of three main components; 1. An internal sealing system, 2. An intelligent, streamlined and hose-less side mounted elevated vacuum pump, and 3. A liner incorporating phase change material to regulate residual limb temperature and perspiration.

METHOD

Subjects: Forty-Five transfemoral amputees fit with the NSS were included in various parts of the testing procedures.

Apparatus: The Prosthetics Evaluation Questionnaire (PEQ) (Legro 1998) was administered to identify changes in the validated scales compared to the subjects' previous suspension system. Additional surveys were used to further probe into the differences between socket systems. A gait mat was used to collect kinetic data during level ground walking. A video camera was used to record and quantify additional functional performance outcomes.

Procedures: A variety of prosthetic socket styles and suspension methods were used by the total subject population at the time of enrollment in the study. Following enrollment and initial assessment of outcomes, subjects were fit was the NSS. The shape of the limb was captured by scanning over the liner worn by the subjects using the Omega scanner. A 5-7% reduction of volume total surface bearing socket was made for all subjects.

Non-PEQ survey responses were collected after 30 days post-delivery of the NSS (n=45). PEQ responses from a subset (n=9) of the entire study population were collected immediately before being fit with the NSS and one year following the fitting.

Temporal and spatial gait data was collected from two transfemoral amputee subjects with their previous socket system prior to being fit with the NSS as well as during a 30-day follow up appointment after delivery of the NSS.

Data Analysis: PEQ responses for individual questions were calculated and grouped into the 9 validated scales according to the questionnaire directions. Additional survey responses were grouped with similar responses and averages were calculated for the group. Temporal and spatial gait outcomes were processed in the instrumented flooring software.

RESULTS

The PEQ showed moderate to significant improvements for many of the validated scales when comparing the NSS to their previous socket system. No change was found for 2 of the scales.

Additional survey responses from all subjects (n=45) found that over 70% of subjects rated the ease of donning the NSS as excellent/good and 77% reported the donning process as better or the same compared to their previous socket system. Additionally, 70% reported better comfort while the remaining 30 % reported comparable comfort of the NSS compared to their previous socket system. 96% reported better security with the OSS.

Temporal and spatial gait outcomes for one of the two subjects involved in this portion of the study found increased velocity, increased cadence, more symmetric step length, decreased base of support, and decreased double support time. The second subjects result found moderate improvements or no changes for the same outcomes.

DISCUSSION

Qualitative outcome measures from amputee subjects identified improvements in quality of life and overall satisfaction with the prosthetic socket. Subjective feedback from the non-PEQ surveys suggest a larger change would exist in the PEQ scores between the previous socket system and the NSS if subjects were asked to return to their previous socket system and repeat the PEQ after some time.

CONCLUSION

The OSS made significant improvements to quality of life for the subjects. Further research exploring these and additional benefits of the system are warranted.

CLINICAL APPLICATIONS

The OSS provides clinicians and amputees a highly effective and comfortable socket system for transfemoral amputees.

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3D-PRINTED WRIST-DRIVEN ORTHOSIS FOR INDIVIDUALS WITH SPINAL CORD INJURY

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INTRODUCTION

Affordable 3D-printers have created a new toolset that may help improve the fabrication and accessibility of a variety of commercially available orthoses designed to help improve function for individuals with limited mobility. A wrist-driven wrist-hand orthosis (WDWHO) assists in opening and closing of the hand by utilizing wrist flexion and extension, consequently enhancing performance of activities of daily living for individuals with complete and incomplete spinal cord injury (SCI) at the 5th or 6th cervical (C-5 or C-6) levels. Current fabrication methods have been described as time-consuming and laborious, in addition to providing poor comfort, function, and aesthetics for the user (House et al., 1976). These devices can also be expensive due to long fabrication and fitting times. The goal of this research was to pursue an iterative design process with the input of orthotists and users to improve the fabrication, cost, and function of WDWHOs.

METHOD

Computer-aided design software (SolidWorks) was used to model the WDWHO. The devices were fabricated on a MakerBot Replicator 3D-printer, using an affordable bioplastic, polylactic acid (PLA). To improve the design, we completed two phases of testing with orthotists and users. During Phase I, two groups of Prosthetics & Orthotics students were recruited to assemble and provide feedback on the WDWHO. These students, who had recently been trained in the fabrication of traditional WDWHOs, assembled the 3D-printed device with a manual describing the assembly process. After fabrication, participants rated the function, aesthetics, and comfort of the device, completed a survey regarding their experience, and made suggestions for improvement. After each session, the feedback was used to modify the design and fabrication methods. In Phase II testing, participants with a C-5 or C-6 level SCI and prior experience using a WDWHO were recruited for user testing. During the first visit, each participant's upper-extremity function was evaluated and measurements were taken to size the device. Future visits will assess device comfort and function.

RESULTS

The final model of the 3D-printed WDWHO took an average of 5 hours of hands-off printing time and 1.5 hours of hands-on assembly. Total material costs were $10, in comparison to $350 for current commercially available WDWHO. We used padding for comfort and Velcro and elastic straps to secure the device to the user's hand. The modified design improved fit at the forearm, allowed for a three-jaw chuck grasp, and increased the range of motion (ROM) at the thumb by 20º by engaging both the fingers and the thumb in motion during wrist flexion and extension (Fig. 1). During Phase I, the device received average grades of 6.3, 6.6, 6.3, and 9.7 on its function, aesthetics, comfort, and fabrication speed, respectively (1 = slow/poor, 10 = fast/great). Each part of the device was designed for multiple sizes (XS, S, M, L, and XL). From our initial testing with SCI users, these interchangeable sizes have been important as all individuals have required different sizes for each part of the device.

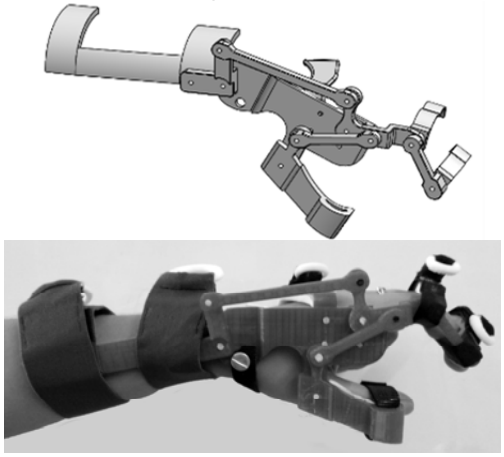

Figure 1. Final design of a 3D-printed WDWHO.

DISCUSSION

Feedback from Phase I participants has improved the function, comfort, aesthetics, and assembly time of the WDWHO to ensure suitability for user testing. Comments made in regards to 3D-printing orthotic devices suggested a "promising method for an inexpensive off-the-shelf orthosis." The increased ROM in the thumb permits a larger grasp, which future testing with SCI users will evaluate for functional improvements. Lastly, initial results from Phase II have confirmed the importance of various sizes for individual components on the device to create a custom and individualized fit. Further testing will evaluate the functional improvements for individuals with SCI and incorporate their comments for future design changes.

CONCLUSION

3D-printing orthoses has the potential to improve WDWHOs and other orthoses due to low material cost, enhanced aesthetics, and easier customizability.

CLINICAL APPLICATIONS

This project aims to improve the design of a traditional WDWHO to reduce complexity and fabrication time, increase availability, and improve appeal to the users.

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3D-PRINTED WRIST-DRIVEN ORTHOSIS FOR INDIVIDUALS WITH SPINAL CORD INJURY

Portnova, A.A.[1], Mukherjee, G.[1], Peters, K.M.[1], Yamane, A.[2], Steele, K.M.[1]
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THE EFFECT OF RISSER SIGN ON THE LIKELIHOOD OF FAILURE WITH BRACING IN ADOLESCENT IDIOPATHIC SCOLIOSIS

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INTRODUCTION

To determine the incidence of surgical curves in children wearing orthoses for the treatment of AIS, and to assess the influence of the Risser sign and compliance on the likelihood of surgery.

METHOD

222 patients were prospectively enrolled in this IRB approved study between the years of 2008 and 2013. All patients were treated with a TLSO-type orthosis, which was either the Boston brace or a CAD/CAM design TLSO with two thermochron data loggers embedded which recorded brace wear each 15 minutes.

RESULTS

We had a total of 164 patients with complete data from the date of brace delivery to the date of either brace discontinuation or surgery. Of the 117 Risser zero patients, 44 had open triradiate cartilages and 73 were closed. Fifty-three of 117 Risser zero patients who have completed bracing (45.3 %) have undergone surgery for progressive scoliosis or have reached surgical magnitudes, compared to two of 28 Risser one patients (7.1%), and none of the 19 Risser two patients. The rate of surgery was 32.9% in the 73 patients who were Risser zero with closed triradiates, nd 65.9% in the 43 patients who had open triradiates. In just analyzing the Risser zero patients, the risk of requiring spinal fusion if a Risser zero child wears a brace at least 15 hours per day was 46.5%. Conversely, the risk of requiring spinal fusion if a Risser zero child does NOT wear a brace an average of 15 hours per day is 33 of 74, or 44.6%. Therefore, wearing a brace 15 hours per day is not effective in Risser zero patients. Only 18 of the 117 Risser zero patients wore their brace 18 hours daily, and only 7 of the 18 went on to surgery (38.9%). The remaining 99 Risser zero patients wore their orthoses less than 18 hours daily, and 46.5% of them went on to surgery. Risser one patients fared better, with no patient who wore their brace greater than 6 hours requiring surgery. None of the 19 Risser two patients required surgery, regardless of their brace wear, but only 3 wore their brace less than 12 hours per day on average. Unfortunately, this study is underpowered to conclude with certainty that bracing is not needed in the Risser 2 population. Those patients with open triradiates were found to go on to surgery in 57.1% of cases despite 15 hours of daily wear. At 18 hours of measured wear, we found that 7 of 9 children (77.8%) progressed to surgery despite being very compliant. In chart review, these 7 compliant surgical patients experienced rapid progression during peak growth velocity, and all had curves 33 degrees or greater when the brace was prescribed. In comparison, there were 9 patients who were Risser zero but had closed triradiates at the time of brace prescription who wore their brace 18 or more hours daily. None of these ten patients experienced surgical progression, and only one had worsening of their curve by 6 or more degrees.

DISCUSSION

We compared our success rate in preventing surgical correction with the article by Lonstein and Winter (1994), which reported the success rate in Risser 0 and 1 patients grouped together with curves ranging from 20 to 50 degrees. In the 20 to 29 degree curve range, Lonstein and Winter report that 9% of patients progressed to surgery. In combining our study's Risser 0 and 1 patients with curves between 25 and 29 degrees (n=44), we found a 13.6% rate of surgery.

CONCLUSION

In conclusion, there is a highly notable relationship between advancing Risser sign and orthotic success. Risser one and two patients were noted to meet with success. All but two Risser one patients (neither of whom reached 6 hours of daily brace wear) avoided surgery. Whether this proves the efficacy of bracing in this group or lends support to the lack of evidence that these children need a brace cannot be determined from this data. Risser zero patients are most likely to progress, and even those that are compliant with brace wear are likely to require surgery if their triradiate cartilages are nonossified at the start of the brace wear period and their curves measure 30 degrees or more.

CLINICAL APPLICATIONS

We recommend that Risser zero patients with closed triradiates should be encouraged to use their braces 18 hours daily, Risser one patients 12 hours daily, and the role for bracing in Risser two patients is unknown. Risser zero patients with open triradiates should be prescribed full time brace wear, and bracing started at 20 degrees. Bracing in a Risser zero/open triradiate patient with a curve of 40 degrees or more is likely futile in preventing progression to a surgical magnitude..

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EFFECT OF OPEN CALCANEUS CARBON COMPOSITE AFO ON GAIT OF AN INDIVIDUAL WITH SPINAL CORD INJURY

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INTRODUCTION

Ankle foot orthoses are often prescribed for individuals with Incomplete Spinal Cord Injury to provide support for weakened musculature, specifically to address excess plantar flexion during initial contact, stabilize the joint for effective push-off during late stance, and prevent toe-drag during swing. (LER Article 14, 16). Traditional AFOs that encompass the calcaneus prevent this "normal" biomechanical process. The purpose of this case study was to investigate the effect on gait wearing bilateral custom solid ankle plastic rigid AFO (SAAFO) versus bilateral rigid Dynamic carbon composite AFO (Allard ToeOFF® AFO) with open calcaneus (RDCC AFO).

METHODS

Subject: 27 year old female who sustained an Incomplete T12 Spinal Cord Injury due to a horse riding accident at the age of 15.

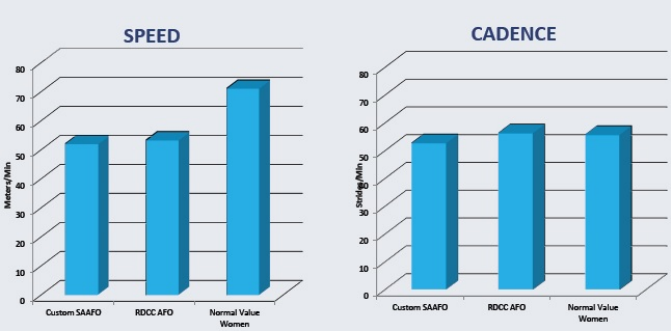
Procedures: Subject was tested in 2 different conditions: 1) Bilateral Custom Solid Ankle AFO and 2) Bilateral rigid dynamic carbon composite AFO with an anterior tibial shell and open calcaneus.

Research Tools: BTS G-WALK Portable Gait Analysis System placed at the L5 vertebral level3.

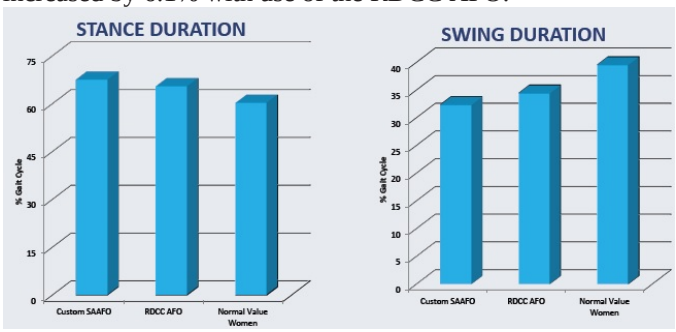
Data Analysis: Averaged temporal-spatial data from 3 walk trials in each condition and then compared averaged data between two conditions.

RESULTS

Overall, the subject performed better in all temporal spatial measures using the RDCC AFO with her performance trending toward normal values for women. Subject's speed increased by 2.4% and cadence increased by 6.38% while utilizing the RDCC AFO.



Stance duration decreased by 3.2% and swing duration increased by 6.1% with use of the RDCC AFO.



Double limb support decreased by 13.6% and single limb support increased by 6.6% with use of the RDCC AFO.

The patient was very confident in the RDCC AFO and did not look as though her gait was affected at all – she appeared to be walking without the need for AFO's. The patient is young and is opposed to donning anything that will limit her ability to dress professionally and ultimately limit shoe choices for her career as an attorney. In addition to affecting gait, compliance issues are also important to the patient.

DISCUSSION

Comparing objective measured values provides guidance for providing the orthotic design with maximum functionality for the patient. The DRCC orthotic intervention provides the maximum function for this patient with an increase in speed and cadence, a decrease in stance phase duration and double limb support while increasing swing phase duration and single limb support. These temporal spatial values tend to indicate more stability and comfort in walking. The RDCC AFO design incorporates a relatively stiff forefoot, restricting dorsiflexion and includes an anterior tibial shell that provides a mechanism whereby forces caused by loading the toe lever can be comfortably distributed to the leg which appears to normalize gait parameters in this patient model. This study has the obvious limits of a case study and gait parameters measured but can give guidance to practitioners in recommending AFO interventions for patients with SCI.

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DISCLOSURE

Thank you Allard USA for use of ToeOFF AFO's (RDCC AFO).
Thank you to my patient for her participation

A review of current clinical practice in five centres in the UK providing dynamic elastomeric fabric orthoses as an orthotic intervention for scoliosis management in children with neuropathic onset scoliosis.

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INTRODUCTION

In the United Kingdom the use of dynamic elastomeric Fabric Orthoses (DEFO) in the treatment of children with cerebral palsy has increased with various subjective outcomes reported, however apart from local internal service audits of service, there has been not been a general review. This paper will report on clinical note interrogation for a number of paediatric rehabilitation services to identify current practice in the area of neuropathic onset scoliosis to provide an indication of the outcomes experienced. The use of these orthoses have been in use for over 15 years and have linked in with the neurodevelopmental therapy principles with interesting outcomes. There is a paucity of evidence, although a handful of single case conference aural presentations and published papers in recent years have reported changes in Cobb angle, improved patient symmetry and compliance. This paper provides an overview to enable clinicians to develop the field of evidence for dynamic orthoses.

METHOD

The study interrogated clinical notes from 5 paediatric rehabilitation centres (mean age of 9 years 1 month, SD 4y7mo) to identify the current practice across the south of England for children with neuropathic onset scoliosis. The research was funded by the British government with interrogation, recording and analysis carried out by the University of Plymouth as part of a Knowledge Transfer Partnership. The author was involved in an advisory role only. University Ethics were obtained for the use of a search matrix to enable data collection over a period of 3 months referencing notes that ranged back up to 7 years. The matrix included 14 key terms including Cobb angle, therapy treatment, diagnosis, usage and types of orthotic intervention and physical abilities including the gross motor functional classification scale (GMFCS).

RESULTS

The study showed a collection of 180 sets of notes which fore filled the inclusion criteria over which 121 children had or were using DEFO suits to manage scoliosis. The demographic showed 53/47% mix of females/ males, with 44% cerebral palsy and 23% with developmental delay. Of the children with cerebral palsy 64% were GMFCS level 4 or 5. Eighty percent of the children presented with a typical “C” shaped curve with the remaining 20% showing an “S” curve. Seventy two percent presented with a mild curve [Medan Cobb Angle 22.6° (SD7.4°)] and 14% moderate [mean Cobb angle 50.2° (SD 8.0°)]. Of the 77 children with confirmed scoliosis 39 (45%) used DEFOs, 18 (23%) used spinal TLSO braces and 20 (32%) used no bracing. Sixty percent were using DEFO suits as a prophylactic intervention whilst 43 used the suits with developing curves. Seven out of eight children with Cobb angle recorded over time show < 10 degrees of curve progression. Five out of fifteen children (33%) had spinal surgery with reported complications.

DISCUSSION

The use of the DEFOs suits in the treatment of scoliosis was more common in the management of less severe curves and as a preventive measure due to the knowledge that the low tone trunks seen in many of the children in particular those with developmental delay and cerebral palsy are known to proceed to require spinal interventions. It known that all children with GMFCS level 4/5 will require surgery (Graham, 2013) and that it currently costs between $50-72K per operation (Diefenbach et al., 2013). Therefore by acting earlier it is possible to prevent or slow scoliosis development (Matthews and Crawford, 2006) and has recently been shown that by stabilising the trunk early on to encourage learned patterning to occur it can improve gross motor function (Curtis, 2015).

By early intervention, the DEFOs encourage learning of body position and can provide translator and compressive forces to enable control of smaller curves without the need for semi / rigid thoracic lumbar sacral orthoses (TLSO) whose compliance is questionable for this population. This suggests that we are treating the unbalanced muscle tone and not the Cobb angle in enable a learned pattern of movement indeed it is understood that the child with cerebral palsy has a different internal model of self, compared to the normal population suggesting that this increases the challenges for correct motor sequential planning (Kurz, 2014). The use of DEFO can therefore improve this due to the feedback feedforward loop and assist in learning balance and improved core stability. The latter being the requirement for good sitting posture.

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CONCLUSION

This paper provides a basis for further research, but does at last enable an overview of outcomes to be acknowledged. Dynamic elastomeric fabric suits for spinal management does have a place in the early intervention in children presenting with scoliosis.

CLINICAL APPLICATIONS

Dynamic Elastomeric Fabric Orthoses can provide spinal correction for children with neuropathic onset scoliosis.

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The Effect of Compliance Monitoring on Brace Use and Success in Patients with AIS: A Final Report

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INTRODUCTION

Previous studies have shown poor compliance with bracing in patients with AIS. The purpose of this study was to determine if physician counseling using compliance monitors improves brace use and decreases curve progression in AIS.

METHOD

222 patients were prospectively enrolled in this study. All patients were Risser 0, 1, or 2, were less than 1year postmenarchal, and had curves between 25 and 45^0 at the time of brace prescription. Patients were placed into 2 groups: Group 1 were aware of the compliance monitor in their brace and were counseled at each visit regarding the downloaded brace usage (n=121). Group 2 were not told the purpose of the monitor in their brace, and physician, orthotist, and patient were blinded to downloaded compliance data (n=101). This report analyzes the comparative data on 160 patients who have completed bracing or had surgery.

RESULTS

88 patients in the counseled and 72 patients in the noncounseled group completed bracing or underwent surgery. Curve magnitude at initiation was 33.1^o in the counseled and 34.3^o in the noncouseled groups. Patients in the counseled group wore their orthoses an average of 13.6 hrs/day throughout their management, while patients in the noncounseled group wore their braces an average of 10.7 hours/day (p=0.0024) In the counseled group that had finished bracing, 58% did not progress > 5^0, while 25% underwent surgery. In the noncounseled group, 45.8% did not progress > 5^0, while 37.5% have progressed to 50^0 or surgery. Forty-nine patients who underwent surgery wore their braces only 10.6 hours/day, compared to 13.1 hours per day in the 111 patients who did not have surgery (p=0.016). The effect of counseling was seen in the Risser 0 (n=112) patients (p=0.0066) but not in the Risser 1 and 2 (n=48) patients (ns).

CONCLUSION

Providing patients compliance feedback and counseling improves brace wear in patients with AIS. Patients who wore their braces more hours/day experienced less curve progression. Patients in both groups who progressed to 50^0 or surgery wore their braces fewer hours over the course of bracing than their successful counterparts.

CLINICAL APPLICATIONS

Compliance monitoring and counseling should become part of the clinical orthotic management of patients with AIS. Counselling is most effective in younger children.

TREATING SCOLIOSIS WITH A 3D PRINTed TLSO
A Prospective, Controlled Study of an Alternative Bracing Option

At the Academy Annual Meeting, Dr. James Policy proposes to present his case study in alternative bracing options for scoliosis patients. Dr. Policy will discuss how 3D printing has enabled more individualized care for scoliosis, the approach to the case study and preliminary feedback from the participants, as well as, ongoing avenues for continued research in scoliosis treatment.

Study Design
Report of a new bracing technique.

Objective
A new means of producing a TLSO brace is described and assessed for compliance and clinical effectiveness in adolescent idiopathic scoliosis (AIS).

Background
Adolescent idiopathic scoliosis (AIS) is a complex 3-dimensional spinal deformity. AIS primarily affects adolescent girls. It has a high risk of progression to the point where surgical intervention is required during any period of rapid growth, such as the adolescent growth spurt from ages 11-14. Brace treatment using a TLSO is the only treatment modality which has been objectively shown to reduce the risk of progression of AIS, and therefor reduce the rate of surgical intervention[1]. In the population of adolescents with scoliosis curves greater than 25 degrees, and with significant skeletal growth remaining, a TLSO can change the risk of progression to the point of needing surgery from 70% to 30%. Bracing is, however dose dependent, and only works if patients can be compliant with brace wear guidelines. optimal brace wear is 18 hours a day, with 12 hours being the minimum time needed to see positive results. Therefor, any alteration of the standard brace which leads to improved compliance while maintaining efficacy should improve patient outcomes.

Bracing Technology

We utilized advanced 3-D scanning, and printing technology to produce a TLSO that is lighter, easier to don, has holes for ventilation, and a superior aesthetic to the current models. These are all things that patients that patients, and parents have complained about in the traditional TLSO. The UNYQ brace provides a solution to many of the common complaints we receive from patients, and families. If our patients are more physically and emotionally comfortable in the brace, then they are more likely to wear it.

Study

We performed a clinical trial of the UNYQ brace to determine if it was safe, and if could effectively treat scoliosis. This was a pilot study to determine wether the UNYQ brace could

[1] http://www.nejm.org/doi/full/10.1056/NEJMoa1307337

provide clinical outcomes on par with a traditional Boston brace. IRB approval was obtained. 60 adolescents with AIS who had curves between 25, and 40 degrees were enrolled in the study. None had received prior treatment. 30 were treated with a UNYQ brace, and a control group of 30 patients were treated with a standard Boston TLSO. All patients had pre-brace, and final x-rays. X-rays were also taken in brace. All patients filled out a questionnaire asking about compliance, level of satisfaction with the brace, and ease of use. Patients were followed until skeletal maturity, brace failure (surgery), or until they outgrew the brace. Some children required more than one brace, so for the second brace they received a standard Boston brace. This study only covered one UNYQ brace per patient.

There was no significant difference in the clinical outcomes between the two groups. There was no significant difference in the degree of correction of the curve while wearing the brace, or at the end of bracing. Three children in each group failed brace treatment and went on to require surgery.

The Patients in the UNYQ brace group found the brace to be more comfortable, and easier to get on/off. The patients who outgrew the UNYQ brace and were given a traditional Boston brace all said they preferred the UNYQ brace.

This study suggests that the UNYQ brace has identical capacity for in-brace curve reduction, and prevention of curve progression when compared to a standard Boston brace. The UNYQ brace has the advantage of greater patient satisfaction. We therefor conclude that the UNYQ brace is a viable option for the treatment of AIS. Further studies are planned utilizing in-brace heat sensors to evaluate patient compliance.

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THE EFFECT OF DAMPING IN PROSTHETIC ANKLE AND KNEE JOINTS ON BIOMECHANICS OUTCOMES: A LITERATURE REVIEW

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INTRODUCTION

In the recent decades, computer-controlled, variable-damping prosthetic ankle-foot and knee have been introduced. Advantages of variable-damping designs over mechanically passive prostheses may include adaptation to various walking speeds and enhanced stability. Foot dampers may play a significant role in the impact transfer of vertical ground reaction force to the knee and hip joints. Some researchers have worked on viscoelastic models of prosthetic foot, comprising of dampers and springs.

Given the growing number of variable-damping components and the broad number of potential outcomes, a systematic review is needed to assess the advantages of damped knee and ankle units over non-damped prostheses. The purpose of this study was, therefore, to provide an overview of the biomechanical outcomes associated with the use of prosthetic knee and ankle with damping mechanisms in individuals with lower limb amputation.

METHOD

A systematic search was performed through PubMed, Science Direct, Web of Science, Cochrane, and Scopus databases from June 1994 to June 2014. The following keywords and their combinations were used for the search: amputee, lower limb, transfemoral, transtibial, above knee, below knee, foot, knee, ankle-foot, prosthesis, artificial limb, hydraulic knee, hydraulic ankle, pneumatic knee, pneumatic ankle, damping, gait analysis, motion analysis and walking. The cited references were also investigated to extend the search.

The level of evidence of each article was assessed using a 13-element checklist developed by Van der Linde et al. for evaluating non-randomized control trials (Van der Linde, 2004). This checklist was originally adapted from two other checklists for quality assessment of randomized controlled trials and included 13 criteria divided into three categories for assessing the selection of patients (A1-A4), intervention and assessment (B5-B9) and statistical validity (C10-13). A criterion scored 1 if the answer was yes or valid and scored 0 if the answer was no or invalid. The criterion scored 0 if it was not applicable. Two reviewers performed the quality assessment independently. Afterwards, the studies were classified as A-level, B-level, or C-level based on total score and positive scores from certain key categories.

RESULTS

The initial search resulted in a total of 243 abstracts, among which 66 papers were duplicated. After applying the inclusion criteria, 16 papers remained for the full text review. Additionally, a reference search of the papers resulted in 10 more papers among which only 4 abstracts met the inclusion criteria. Finally, 20 studies were assessed

Fourteen of the 20 studies scored enough to be classified. Use black and white graphics. Among those, 1 scored as A-level, 8 as B and 5 as C. The main difference between B- and C-level studies was the positive score on the adaptation time with the prosthesis criterion. Ten studied knees and four studied ankles and ranged from 5 to 28 subjects.

DISCUSSION

The A-level study for prosthetic knees (Boonstra et al., 1996) compared an Otto Bock 3R20 mechanical swing phase control knee to a Teh Lin pneumatic swing- phase control knee and found increased walking speed and decreased knee joint range of motion with the latter. However, other B- and C-level studies found no differences in similar outcomes with similar knees. The one B-level study assessing ankle/foot mechanisms found no cadence changes but decreased loading rates for an Echelon foot versus an ESAR foot (Portnoy, 2012).

CONCLUSION

Minor differences were documented with the damped prosthetic knee and ankle joints compared to those without a damper. Additionally, considering the level of studies based on this review, more studies are needed to prove the differences among the various available joints. Overall, the walking speed showed the highest difference when dampers were applied to the leg. Moreover, the few available studies on the prosthetic ankle only were conducted on transtibial amputees. Future work is needed to compare the outcomes with transfemoral amputees as well and to evaluate how the combination of damped knee and ankle joint would affect amputee performance.

CLINICAL APPLICATIONS

Prescription of knee and foot/ankle components becomes more challenging as devices become more complex. Ongoing research is needed related to biomechanical outcomes in order to properly match component capability to patient need.

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PEDIATRIC PARTIAL FOOT PROSTHESES: A NEW TREATMENT OPTION

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INTRODUCTION

Documentation of pediatric partial foot amputation (PFA), prosthetic intervention and effectiveness of treatment is insufficient. However, recommendations regarding pediatric prosthetic intervention advise downsizing, sequenced complexity and a modular design that does not interfere with an increased activity level.[2] In the general population PFA is the most common amputation surgery with 2 per 1000 affected.[4] Transmetatarsal or mid-tarsal amputations account for approximately 24% of PFAs.[3] In the pediatric population 40% of amputations are attributed to trauma.[8] Lawn mowers and household accidents account for the majority of the partial foot amputations in the pediatric population[8.] Current pediatric treatment options mimic those for adults with the extent of the intervention proportional to the extent of tissue lost.[3] More recently it has been recommended that any amputation involving the metatarsal heads or proximal structures requires a prosthetic intervention that extends proximal to the ankle.[6] A prosthesis utilizing a custom fit rigid dynamic carbon composite (DCC) ankle foot orthosis structure to aid in the restoration of gait has been proposed for the adult PFA patient. [7] By extending above the ankle the prosthesis aids in the progression of the center of pressure along the foot and restores the biomechanics of walking.[6]

METHODS

A prosthetic design for treating the pediatric partial foot amputee that restores gait function by addressing the biomechanical deficits is proposed. A custom fit rigid DCC with carbon anterior shell AFO customized with a toe-filler type socket with wedging, lifts and posting are the components of the proposed prosthesis. Until recently there was not a custom fit option for providing a reliable custom fit rigid DCC structure in which to fabricate a custom prosthesis for the pediatric population. The new custom fit rigid DCC is a prefabricated full carbon foot plate, rigid lateral strut and carbon composite anterior shell. The footplate is rigid with a tapered rocker built into the distal section with a flexible posterior section and a rigid stable midfoot. This design aids in restoring gait by allowing for a controlled plantarflexion moment at initial contact, a stable midstance and a controlled tibial advancement through terminal stance, while maintaining a 3rd rocker rollover and providing propulsion at terminal stance. This system is combined with a custom molded toe filler type prosthesis that is aligned with wedges, posts and lifts to maximize functional outcomes. This system addresses the biomechanical deficits of the PFA and the DCC is designed to have varying degrees dynamic function by style and size. The ability to customize the socket, alignment and interface helps to protect the skin of the residuum while the dynamic function can be customized for functional needs.

RESULTS

The pediatric prosthetic design is proposed based on the outcomes of the adult treatment option with similar outcomes expected. This prosthetic design has been used with adult PFA patients since 2010 the anecdotal results are positive. Patients report increased mobility and decreased skin breakdown.

DISCUSSION

Research on specific effects on gait function utilizing the proposed PFA DCC design need to be conducted. Preliminary data regarding use of the DCC AFO in the pediatric population indicates that a dynamic response carbon AFO, similar to the rigid DCC design, provides improved function in running, jumping and walking performance while Gross Motor Function Measure was also improved. [1] Similar outcomes are expected with a PFA DCC prosthesis due to the similarity of the gross structure and function of the rigid DCC design.

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DISCLOSURE

Vincent DeCataldo, BOCPO, NJ LPO is employed by Allard USA manufacturer of dynamic carbon composite AFOs.

The Effectiveness of the Ertl Bone Bridge Procedure: A Systematic Review

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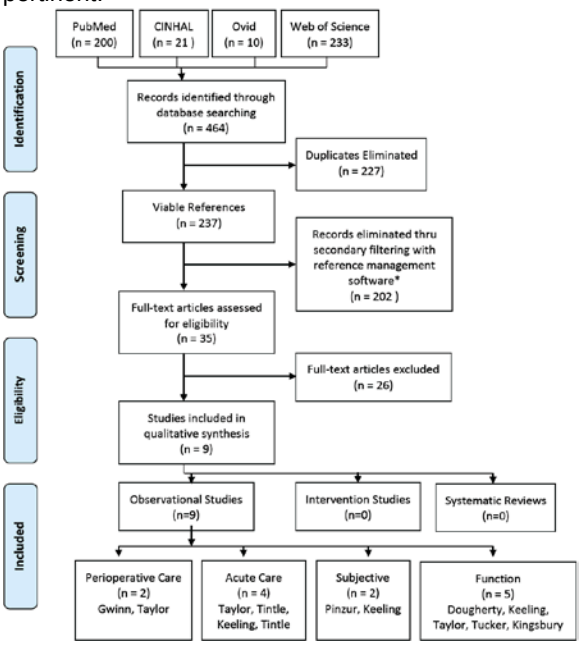
Indiana University, University of South Florida, OP Solutions, Veterans Affairs, EACE

INTRODUCTION

Physical outcomes have been reported to be equivalent to limb salvage. Amputation and use of a prosthesis could be further enhanced with an improved amputation technique. The Ertl bone bridge procedure has been reported to provide a mechanistic advantage to the prosthetic user by providing a weight bearing surface, while limiting painful tibio-fibular motion. The Ertl procedure could lead to superior outcomes compared to a traditional amputation technique. However, there also maybe complications associated with this technique. This systematic literature review (SR) was undertaken to determine if commonly held views regarding the benefits of the bone bridge procedure are supported by the literature.

METHOD

Four databases were searched for articles pertaining to surgical strategies specific to a bone bridge, Ertl or osteomyoplastic procedures of the transtibial amputee. A total of 35 articles were identified as potential articles. Authors included methodology that was applied to the separate topics. Following identification, articles were excluded if they were determined to be low quality evidence or not pertinent.



RESULTS

Nine articles were identified to be pertinent to one of the topics: *Perioperative Care, Acute Care, Subjective Analysis and Function.* Two articles sorted into multiple topics. Two articles sorted into the *Perioperative Care* topic, 4 articles sorted into the *Acute Care* topic, 2 articles sorted into the *Subjective Analysis* topic and 5 articles sorted into the *Function* topic.

DISCUSSION

There are no high quality (level one or two) clinical trials reporting comparisons of the bone bridge procedure to traditional methods. There is limited evidence supporting the clinical outcomes of the bone bridge procedure. There is no agreement supporting or discouraging the perioperative and acute care aspects of the bone bridge procedure. There is no evidence defining an interventional comparison of the bone bridge procedure. Most articles in this SR identified the bone bridge procedure to be equivalent to a traditional technique. This SR is currently under review for publication. This group is pursuing funding to conduct a randomized clinical trial (RCT) to compare the Ertl bone bridge to the standard of care technique. The proposed RCT will include physical functional long-term outcomes.

CONCLUSION

The Ertl bone bridge procedure may have physiological and functional merit. The bone bridge technique is reported to increase tourniquet and surgical time. There is not agreement on acute complications related to a bone bridge technique. Perspective measure of function was reported as equivalent to traditional measures. No physical functional performance outcomes have been used to compare the bone bridge to traditional amputation. Formal level one and two clinical trials will need to be considered in the future to guide clinical practice.

CLINICAL APPLICATIONS

Amputation is currently a viable (and could be an improved) outcome to limb salvage, when amputation is considered. Mechanistic advantage is an important first step to validating any procedure. However, higher-level evidence must be identified and sought to substantiate that procedure. It is clinically imperative for a prosthetist to know evidence based outcomes regarding procedures they may recommend to their patient populations and surgeons with whom they collaborate and support. The Ertl bone bridge is a procedure that could improve outcome, but knowing the current state of and quality of evidence is the starting point to clinical understanding and practice guidelines.

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American Academy of Orthotists & Prosthetists
42nd Academy Annual Meeting &
Scientific Symposium
March 9 – 12, 2016

The Effectiveness of the Ertl Bone Bridge Procedure: A Systematic Review

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Indiana University, University of South Florida, OP Solutions, Veterans Affairs, EACE

Keeling JJ, Comparison of functional outcomes following bone bridge in TTAs, JBJS, 2013

VALIDITY OF MODUS FUNCTIONAL LEVEL SCORE AND OTHER MEASURES FOR ESTIMATING CMS FUNCTIONAL CLASSIFICATION (K-LEVEL) OF LOWER LIMB AMPUTEES

Godfrey, B.[1,2], Berdan, J.[1,2], Nuntapreda, M.[1], Engelen, R.[1], Rosenbaum-Chou, T.[3]

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INTRODUCTION: The Medicare Functional Classification Level (MFCL) is the classification system utilized by clinicians to describe the functional level of amputees. The MFCL "K-Level" is commonly determined by the clinician's clinical judgment, patient self-report of activity, physical examination, and observation of gait. However, no standardized method exists for interpreting MFCL and patient self-report of activity may be inaccurate. [1] The American Academy of Orthotists and Prosthetists (AAOP) stated the need to move from "subjective method of prosthetic prescription towards an objective evidence-based foundation for prosthetic practice."[2]

The objective of this study was to determine the most valid functional test in determining K-levels in transtibial amputees. This study evaluated the Modus CMS Functional Level Score (Modus Score), daily steps, peak cadence, six-minute walk test (6MWT), and Amputee Mobility Predictor with Prosthesis (AMPPRO).

METHOD: Following, IRB approval, subjects were recruited from the George E. Wahlen Department of Veterans Affairs Amputee Clinic. The inclusion criteria was transtibial amputation, able to walk > 3 steps with prosthesis, ≥ 21 years old, ≥ 1 year post amputation, and a well –fitting functional prosthesis. Visit 1 involved obtaining consent, performing the 6MWT, performing AMPPRO, and applying the StepWatch and GPS to the prosthesis (Figure 1). The subjects wore the devices for two weeks. Absolute differences between week 1 and week 2 were used for determining repeat reliability of the real world metrics.

The Modified Clinical K-level was the functional level the VA physicians' thought was most correct for the patient, and therefore, was the reference by which the other measures were compared. VA physicians, Bradeigh Godfrey, DO and Jeff Berdan, DO, used the number of steps in community (StepWatch and GPS), steps/day (StepWatch), peak cadence (StepWatch), and environmental barriers traversed (GPS and StepWatch) for the research subjects' first 6-10 days [1], as well as their clinical expertise, to determine the Modified Clinical K-level of the subject. Drs. Godfrey and Berdan were blinded to the subject's Modus Score, 6MWT, and AMPPRO results.

RESULTS: Data was collected on 27 subjects. Using Canonical Linear Discriminant Analysis, the Modus Score had the highest correlation to the Modified Clinical K-level, r=0.96, p<0.001 (Figure 2). The others also significantly correlated but to a lesser degree: AMPPRO (r=0.93), 6MWT (r=0.89), peak cadence (r=0.89), and daily steps (r=0.76).

Only Modus Score had no overlap in scores between K2 and K3 (Figure 1). When using basic rounding of decimal values, the Modus Score was 100% accurate in differentiating patients as K2 or lower and K3 or higher. Its overall accuracy / sensitivity was 85%. There are no standard methods of converting the other metrics to K-levels.

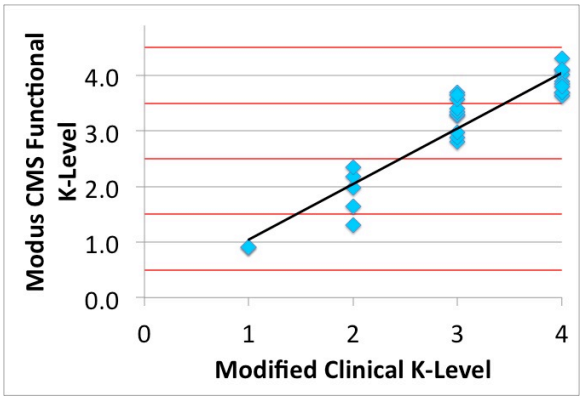

Figure 1 – Modus Score vs Modified Clinical K-Level. Modus Score was 100% accurate in differentiating K2s from K3s.

Repeat reliability of the real world metrics was as follows: Modus Score (5% ± 11%), daily steps (21% ± 15%), and peak cadence (9% ±T 10%).

DISCUSSION: The Modus Score correlated the most strongly with the Modified Clinical K-level. In addition, the Modus Score had greater repeat reliability than daily steps and peak cadence indicating it has greater potential to capture clinically relevant change. The other metrics also significantly correlated with K-level but had more overlap in scores between each K-level.

CONCLUSION / CLINICAL APPLICATIONS: The Modus Score appears to be a clinically feasible tool for aiding clinicians in their functional evaluations of their patients.

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American Academy of Orthotists & Prosthetists
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Classification and Measurement of Lower Limb Amputee Locomotion Activity

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INTRODUCTION

The aim of this research is to observe how amputees actually use their prosthesis by classifying and counting the number of steps they take during different locomotion activities (i.e., walking straight on level ground, up stairs, down stairs, up ramps, down ramps, turning left, and turning right) that occur daily.

METHOD

Subjects: 7 lower limb amputees provided informed consent to participate in this IRB-approved protocol.

Instrument: A custom, two-layer, two-board circuit small enough to fit inside a standard prosthetic pylon was fabricated to observe amputee movements. The instrument included: a 32-bit microcontroller (PIC32MX), a battery, a removable 4-Gb secure digital card for data storage, and a six-axis inertial measurement unit (tri-axial accelerometer and tri-axial rate gyroscope). Data from each axis was recorded continuously at 100 Hz.

Procedures: The instrument was placed inside each participant's pylon by a certified prosthetist. Participants were then asked to walk a defined validation course (~10 minutes at self-selected speed) while followed by a study investigator collecting locomotion data with a video camera. The validation course was designed to provide a sufficient number of steps (~30) for each locomotion activity in order to adequately train the pattern recognition algorithm. Subjects were then free to pursue their typical daily activities (field observations) for the next several days. Subjects then returned to the laboratory where the instrument was removed by the prosthetist.

Data Processing: Raw data was filtered to reduce noise (Butterworth filter) and correct gyro drift (Complementary filter). Filtered signals were separated into gait phases to identify the timing of toe off, mid-swing, and heel strike for each gait cycle. Key features were then extracted and used by a support vector machine pattern recognition algorithm to classify the locomotion activity of each step (straight walking on level ground, up stairs, down stairs, up ramps, down ramps, turning left, and turning right).

Data Analysis: After processing, instrumented pylon data from the validation course was used to calculate algorithm accuracy for each locomotion activity by comparison with video observations. Data from the subsequent field observations was used to calculate step counts for each locomotion activity.

RESULTS

The algorithm accuracy for all locomotion activities combined was 97.7±2.4 % (see Table 1 for details by specific activity). The total step count during the observation period was 5206±2040 over a period of 40.1±11.6 hours. The step counts for each activity, as a percentage of the total steps, is shown in Table 1. In general, 83% of all steps were taken while walking in a straight line, 9% while turning, 5% on stairs, and 4% on slopes.

	ALGORITHM ACCURACY	ACTIVITY CLASSIFICATION
Straight	99.8 ± 0.4 %	82.9 ± 3.6 %
Turn right	99.0 ± 1.1 %	4.2 ± 1.0 %
Turn left	99.0 ± 1.7 %	4.5 ± 1.9 %
Slope down	97.1 ± 3.3 %	2.1 ± 1.0 %
Slope up	92.7 ± 2.3 %	1.5 ± 0.4 %
Stair down	97.9 ± 2.1 %	2.6 ± 1.0 %
Stair up	98.4 ± 1.6 %	2.2 ± 0.8 %

Table 1. Algorithm accuracy (percentage correctly identified) and overall step counts (percentage of total steps) during typical daily activities.

DISCUSSION

Different daily tasks, such as a walking bout through a parking lot or while shopping in a convenience store, may require a significantly different percentage of locomotion activities (Glaister, 2007). The results presented here, encompassing a range of daily tasks, suggest that development and prescription of prosthetic devices that facilitate maneuvering or walking on different terrains (slopes or stairs) is warranted.

CONCLUSION

A support vector machine pattern recognition algorithm accurately identified the activities of lower limb amputees. In a small sample (n=7) over several days, nearly one in five of all steps taken involved turning, walking on slopes, or walking on stairs.

CLINICAL APPLICATIONS

Next generation prostheses for lower limb amputees should facilitate multiple locomotion activities in addition to straight line walking.

ACKNOWLEDGEMENT

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3D-Printed Prosthetic Inserts to Extend Socket Life

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INTRODUCTION

Residual limb shape change occurs both throughout the day, and over the lifetime of a socket. Persistent shape changes in a limb are often accommodated with prosthetic socks (D'Silva 2014) or padded inserts. If shape changes are large, a new socket may need to be fabricated. A socket insert may be able to extend the life of a socket by decreasing the number of socks worn and better matching a clinically desirable socket. The purpose of this study was to evaluate the feasibility and accuracy of hard inserts fabricated with a 3D printer. We also investigated integrating sensors into the inserts for potential outcomes monitoring.

METHOD

Five people with transtibial amputation wore a test prosthesis consisting of an enlarged duplicate of their practitioner prescribed socket plus a 3D printed insert.

Subjects' normal prostheses were digitized with a precision 3D scanner (Platinum Arm, Faro). The scanned socket shape was digitally enlarged using a CAD program (Geomagic, 3D Systems) by applying a uniform offset of 1.8mm. A test socket was then fabricated using the enlarged profile (Fig. 1). A socket insert was created in CAD as the difference between the scanned original and the enlarged duplicate socket profiles. The insert was fabricated with a 3D printer (Objet30 Pro, Stratasys) from a rigid polymer with properties similar to Delrin®.

Subjects wore the enlarged duplicate socket with insert for four weeks. The inside surface was scanned at the beginning and end of the four-week wear period. Insert geometries were then compared to participants' original socket geometries using a custom Matlab script (Sanders 2011).

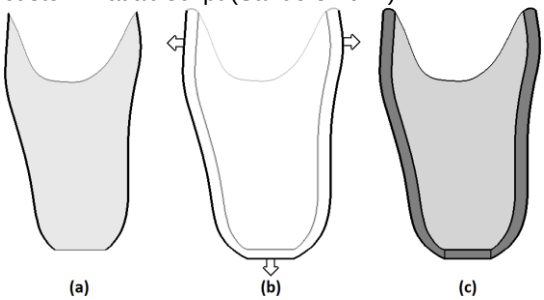

Figure 1: Each participant's prosthetic socket (a) was offset to create an enlarged duplicate (b). An insert (c) was created to fill the void between (a) and (b).

Proximity sensors (limb-socket distance) and force sensors (activity) (Sanders 2015) were integrated into inserts, using cutouts and channels to position the sensors flush with the inside surface (Fig. 2).

RESULTS

For the five subjects tested fit quality (i.e., difference between the insert and original socket shape) improved over the four-week wear period. Compared to the original socket total volume, new inserts were 0.38% smaller (mean radial error -0.11±0.23 mm) while worn inserts were 0.09% smaller (mean radial error -0.03±0.15 mm) (Table 1). Over the four-week trial period, no signs of abnormal fatigue or failure were noted. Sensors integrated into the inserts showed good durability and low signal noise (Fig. 2).

Table 1: Shape comparisons between installed inserts and the original socket shape (n=5).

	Radial Error (mm)		Vol Error (%)	
	New	**Worn**	**New**	**Worn**
1	-0.12 ± 0.16	-0.02 ± 0.16	-0.43	-0.06
2	-0.13 ± 0.19	-0.02 ± 0.23	-0.38	-0.04
3	-0.09 ± 0.18	-0.03 ± 0.11	-0.29	-0.11
4	-0.04 ± 0.25	-0.02 ± 0.12	-0.13	-0.05
5	-0.19 ± 0.36	-0.05 ± 0.13	-0.66	-0.18

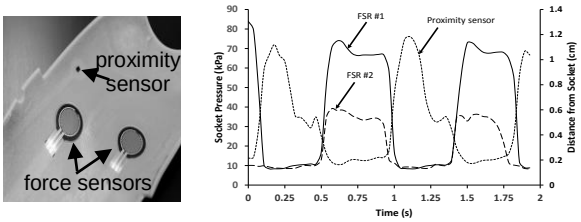

Figure 2: Left: Force (FSR) and proximity sensors in insert. Right: Exemplary data collected during walking.

DISCUSSION

This study showed that 3D printed inserts for prosthetic sockets are both feasible and accurate. There may be a break-in period for the inserts since they tended to seat in place with use. Sensors integrated effectively into the inserts and may prove useful for outcome assessment.

CLINICAL APPLICATIONS

3D printers are becoming increasingly available that offer similar precision to the model used in this study for a fraction of the cost. Thus, it may soon be possible to fabricate inexpensive inserts and extend the life of a socket.

Inserts in this study were designed with a uniform thickness. However, non-uniform inserts could likely be customized to the patient using design software (e.g. OMEGA® Tracer; Canfit™). Regional shape changes may further enhance socket fit.

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How Does Socket Size Affect Limb Volume, Activity, Gait and Comfort?

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INTRODUCTION

People with trans-tibial limb loss typically experience a reduction in their limb volume over time. This reduction in volume causes the socket to become oversized and may adversely affect clinical outcomes. Even sockets oversized by as little as 1.0% have been shown clinically distinguishable from properly-sized sockets (Sanders, 2012). The purpose of this study was to examine on people with trans-tibial limb loss how daily limb fluid volume loss, daily activity, gait, and comfort were affected by use of an oversized socket compared with a normal socket.

METHOD

Participants: Volunteers with trans-tibial limb loss who wore a prosthesis at least 4 h/day participated.

Procedures: Two prosthetic sockets were fabricated for each participant by a research prosthetist. One was fit to be comfortable with 3.0mm or less sock thickness (normal), the other was made to be 5.0% larger (oversized). 5.0% corresponds to about a 1.8mm uniform increase and has been characterized as an increase capable of transitioning a 'good' fit to just an 'acceptable' one (Fernie, 1982). Participants wore each socket for a four-week period and then came to the lab for a day of testing. Morning and afternoon limb fluid volume were monitored during 35-minute active test sessions using bioimpedance analysis (Sanders, 2015). Both distal and total residual limb fluid volume were assessed. Activity was monitored between sessions using an Actigraph GT3X+ accelerometer mounted to the prosthetic limb. Gait speed, cadence, prosthetic limb step length, step width, and step time were evaluated using a GAITRite™ walkway (McDonough, 2001). Socket comfort was determined using Socket Comfort Score (Hanspal, 2003). Satisfaction, ambulation, residual limb health, utility, and well-being were evaluated using subscales of the Prosthesis Evaluation Questionnaire (Legro, 1998). Collected data were analyzed to compare differences in outcomes between the oversized and normal socket conditions.

RESULTS

Test results showed that of the variables assessed, only morning-to-afternoon residual limb fluid volume loss in the distal section of the limb and Utility differed significantly between the oversized and normal socket conditions (Table 1). The average difference in limb fluid volume loss rate for the oversized compared to the normal socket was 2.5 %/h.

DISCUSSION

The 5.0% size difference between the oversized and normal socket was not sufficient to induce significant changes in gait, activity, or comfort measures (other than Utility), but was sufficient to cause a significant change in morning-to-afternoon distal limb fluid volume loss. This result suggests that distal limb fluid volume is highly sensitive to socket oversizing. Because oversizing was not severe enough to cause a meaningful change in socket comfort outcomes, we conclude that increased morning-to-afternoon distal limb fluid volume change may serve as a precursor to compromised socket fit and thus an effective indicator of imminent need for socket modification.

Table 1. Two-tailed *t*-test significance results for the oversized socket compared with the normal socket. Bold text= mean greater for oversized socket.

DAILY LIMB FLUID VOLUME LOSS			
Total Limb	**.188**	**Distal Region**	**.014**
DAILY ACTIVITY			
% Light	**.324**	% Moderate	.261
% Vigorous	.824	**% Very Vigorous**	**.859**
Step Count	.755		
GAIT			
Speed	.784	Cadence	.374
Step Length	.138	**Step Width**	**.491**
Step Time	.428		
COMFORT			
SCS	.370	Satisfaction	.148
Ambulation	.092	RL Health	.134
Utility	.049	Well-Being	.090

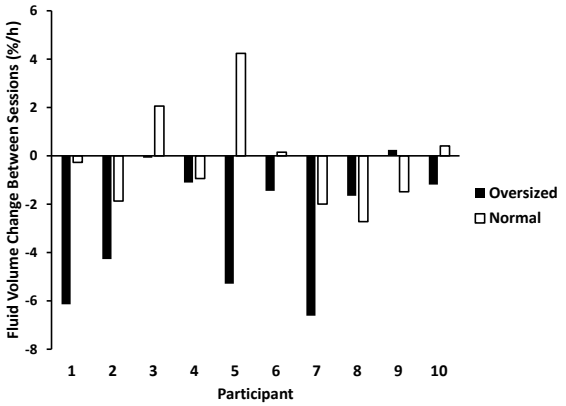

Figure 1. Limb fluid volume loss rate in distal region.

CLINICAL APPLICATIONS

Morning-to-afternoon distal limb fluid volume loss may be indicative of socket oversizing and the imminent need for socket modification. Clinical tools to detect volume changes may help inform need for socket changes.

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A Computational Tool to Enhance Liner Selection

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INTRODUCTION

With over 60 prosthetic liners available, it can be challenging for a practitioner to choose the best liner for each patient. Previous research has investigated six distinct mechanical properties of 25 prosthetic liners (Cagle, 2015), however, it is unclear how these materials respond to the compound loading experienced in normal use. The purpose of this research was to create an accurate Finite Element Model (FEM) to estimate how different liner materials influenced load transmission to a residual limb.

METHOD

Magnetic Resonance Images (MRI) were taken of a residual limb within a prosthetic socket. From these images, a FEM was created that included the distal third of the thigh and the residual limb. Components included skin plus muscle, patellar tendon, liner, and socket. Material data for the soft tissues and prosthetic socket were taken from the scientific literature. Force data reflected pylon loads collected during the weight-acceptance phase of gait.

Three different liner materials were modeled. Liner property data were from material tests collected in the lab and then fit to a non-linear hyperelastic material model. The liners chosen represented extremes of available liner properties – hard-slick, soft-slick, and soft-sticky. Frictional slipping and surface separation was modeled both between the liner-socket and the limb-liner interfaces.

Load transmission was evaluated by comparing slipping, pressure, and frictional shear stresses at the limb-liner interface for the three liner materials.

RESULTS

Slipping was more pronounced between the limb and liner than the liner and socket, particularly over the lateral wall and the tibia. Slip between the limb and liner over the tibia was 1.2mm, 1.1mm, and <0.1mm for hard-slick, soft-slick, and soft-sticky liners, respectively.

Each liner tended to distribute socket loads in a unique manner. The hard-slick liner transmitted loads through focused pressures in targeted regions such as the patellar tendon. The soft-slick liner transmitted loads through pressures over a more distributed area (Figure 1). The soft-slick liner experienced the greatest deformation and thinning under high loads. Peak stresses were not as well distributed compared to the hard-slick or soft-sticky liners, and skin contact pressures were increased in regions where loads were typically undesirable, most notably around the fibular head and distal tibia.

The soft-sticky liner shifted load transmission compared to the slick liners. Peak pressures were decreased by 19% in target loading areas (e.g., the patellar tendon), while no increase was seen in non-targeted regions. Loads were transmitted through frictional shear stresses more evenly distributed over the limb compared with the slick liners (Figure 2).

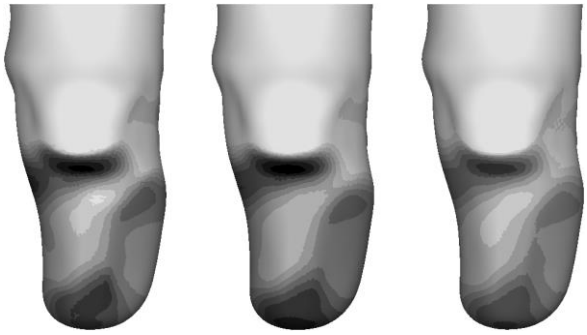

Figure 1: Pressures for hard-slick (left), soft-slick (middle), and soft-sticky (right) liners

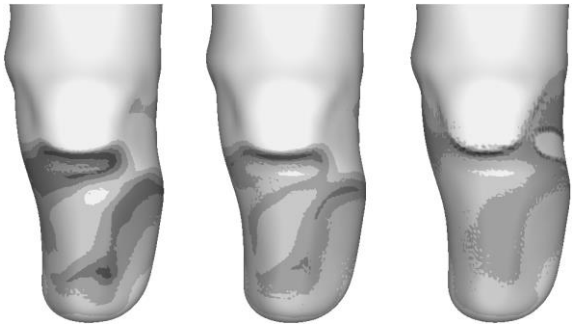

Figure 2: Frictional shear stresses for hard-slick (left), soft-slick (middle), and soft-sticky (right) liners

DISCUSSION

Limb-liner interface stress distributions can be manipulated by adjusting liner material properties. Desirable loading is best achieved when stiffness and friction are complimentary (stiff-slick or soft-sticky). Further research should investigate how results change with heat and friction due to sweat.

CLINICAL APPLICATIONS

Liner selection can be improved by tailoring a liner's method of transmitting ambulatory loads to an individual user's residual limb. This model will be used to evaluate all 25 prosthetic liners measured to date and integrated with a free online tool, the Prosthetic Liner Assistant (www.LinerAssist.org).

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The effect of having different comorbidities in addition to an amputation on finding employment through VR services

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INTRODUCTION

Vocational Rehabilitation (VR) services provide services to individuals with various disabilities who need assistance in obtaining gainful employment. These services are administered through state vocational rehabilitation programs and through the Veterans Affairs Vocational Rehabilitation and Employment program.

People with amputation can receive funding for prosthetic care through VR services when it assists the individual in obtaining employment and aids them in meeting the essential skills of that occupation. In this scenario, prosthetic care is administered by certified prosthetists in collaboration with the rehabilitation counselor assigned to the individual's case.

VR services are provided in all fifty states and records for each individual case are combined into a national database (RSA-911). RSA-911 data contains each person's demographics, type of disability (e.g. amputation), all services provided through VR, the cost of those services, and employment outcomes. Therefore, the RSA-911 database provides a national sample with relevant outcome measures (e.g. employment) that could be used to demonstrate the effectiveness of prosthetic care to third party payers.

The purpose of this research was to define the effect of having amputation and comorbidity through VR services on employment outcomes.

METHOD

Subjects: Any individual that listed amputation as the primary impairment, received vocational rehabilitation services, and was entered into the RSA-911 database between 2007 and 2012.

Apparatus: The RSA-911 database was used to retrospectively look at the effect of having an amputation with comorbidities on employment outcomes.

Procedures: RSA-911 data was combined across years 2007 and 2012 then filtered to include only those with amputation as the primary impairment and with VR cases closed with or without an employment outcome. A filtering algorithm (rehabilitation technology provided by an outside vendor + total cost > $4000) was developed to determine the number of people that received a prosthesis funded by VR services.

Data Analysis: A forward model logistic regression analysis determined best predictors of employment. Those potential predictors include gender, race, presence of comorbidity, all thirteen services provided by VR, and receipt of prosthesis. This was necessary so that the model could correct for the potential confounding effect of another service. Independent t-tests tested for significant differences between hourly wages at closure for those that did or did not receive prosthesis through VR services. A Pearson Chi-Squared analysis tested if the receipt of prosthesis had a significant effect on whether or not public support was a person's primary source of income after VR services were closed. Significance was set at $p < 0.05$.

RESULTS

There was a significant negative effect of having comorbidities in addition to amputation on attaining employment through VR services. After controlling for all other demographic and VR service factors ($p < 0.001$). Individuals with multiple amputations were 1.5 times less likely to gain employment, while individuals with amputation and drug abuse or dependence (other than alcohol) were 3 times less likely to gain employment. Compared to just individuals with amputation with no comorbidities.

DISCUSSION

There was an overall negative effect of employment, when individuals with amputation have comorbidities.. These findings were significant after controlling for all other potential confounding variables such as gender, race, and other services provided through VR. The dataset is limited in that the level of amputation is not specified making it unclear the ratio of upper to lower limb prostheses being provided. Despite this limitation, the data does demonstrate that having multiple comorbidities complicates the rehabilitation process at all levels. Access to information can assist prosthetists in developing more thorough patient care, knowing some cases might be more complicated than they appear.

CONCLUSION

VR services should continue to pay for prostheses that are tailored to the specifics of the individual's vocational needs but need to be cognizant that a more thorough rehabilitation plan needs to be in place.

CLINICAL APPLICATIONS

This research provides justification for a more thorough approach to prosthetic care via prosthetic clinics. These findings show when comorbidities are present that a prosthesis is just one part of the rehabilitation process to achieve employment.

FUNDING ACKNOWLEDGEMENT

The effect of having different comorbidities in addition to an amputation on finding employment through VR services

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Provision of a prosthesis through vocational rehabilitation services predicts positive employment outcomes

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INTRODUCTION

Vocational Rehabilitation (VR) services provides services to individuals with various disabilities who need assistance in obtaining gainful employment. These services are administered through state vocational rehabilitation programs and through the Veterans Affairs Vocational Rehabilitation and Employment program.

People with amputation can receive funding for prosthetic care through VR services when it assists the individual in obtaining specific employment and aids them in meeting the essential skills of that occupation. In this scenario, prosthetic care is administered by certified prosthetists in collaboration with the rehabilitation counselor assigned to the individual's case.

VR services are provided in all fifty states and records for each individual case are combined into a national database (RSA-911). RSA-911 data contains each person's demographics, type of disability (e.g. amputation), all services provided through VR, the cost of those services, and employment outcomes. Therefore, the RSA-911 database provides a national sample with relevant outcome measures (e.g. employment) that could be used to demonstrate the effectiveness of prosthetic care to third party payers.

The purpose of this research was to define the effect of receiving a prosthesis through VR services on employment outcomes, hourly wage at closure, and public assistance.

METHOD

Subjects: Any individual that listed amputation as the primary impairment, received vocational rehabilitation services, and was entered into the RSA-911 database between 2007 and 2012.

Apparatus: The RSA-911 database was used to retrospectively look at the effect of having an amputation on employment outcomes.

Procedures: RSA-911 data was combined across years 2007 and 2012 then filtered to include only those with amputation as the primary impairment and with VR cases closed with or without an employment outcome. A filtering algorithm (rehabilitation technology provided by an outside vendor + total cost > $4000) was developed to determine the number of people that received a prosthesis funded by VR services.

Data Analysis: A forward model logistic regression analysis determined best predictors of employment. Those potential predictors include gender, race, presence of a comorbidity, all thirteen services provided by VR, and receipt of a prosthesis. This was necessary so that the model could correct for the potential confounding effect of another service. Independent t-tests tested for significant differences between hourly wages at closure for those that did or did not receive a prosthesis through VR services. A Pearson Chi-Squared analysis tested if the receipt of a prosthesis had a significant effect on whether or not public support was a person's primary source of income after VR services were closed. Significance was set at $p < 0.05$.

RESULTS

There was a significant positive effect of receiving a prosthesis on attaining employment through VR services after controlling for all other demographic and VR service factors ($p < 0.001$). People that received a prosthesis through VR services were less likely to have public support as their primary source of income (90.2% vs. 87.9%, $p = 0.003$) and have higher hourly wages when they were employed (13.37 ± 9.66 $/hr vs. 12.47 ±7.24 $/hr, $p < 0.001$).

DISCUSSION

There was an overall positive effect of employment, wages, and reduction of public support when individuals with amputation are provided a prosthesis through VR services. These findings were significant after controlling for all other potential confounding variables such as gender, race, and other services provided through VR. The dataset is limited in that the level of amputation is not specified making it unclear the ratio of upper to lower limb prostheses being provided. Despite this limitation, the data does demonstrate that the use of state and federal monies for prostheses of any level better predicts that individual achieving employment, they achieve higher wages, and they are less likely to have public support as their primary income. All positive outcomes.

CONCLUSION

VR services should continue to pay for prostheses that are tailored to the specifics of that individual's vocational needs.

CLINICAL APPLICATIONS

This research provides justification for VR services to continue to pay for prosthetic services via prosthetic clinics and demonstrates improvements in outcomes when the prosthesis is designed to meet the vocational needs of the prosthesis user.

FUNDING ACKNOWLEDGEMENT

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FROM VILLAINS TO HEROES: A CONTENT ANALYSIS ON THE MEDIA PORTRAYAL OF PEOPLE WITH LIMB LOSS

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INTRODUCTION

Classic villains and heroes such as Captain Hook and Luke Skywalker are a few examples of how characters with amputations have been displayed in a negative and a positive manner. The portrayal of people with amputations in film has influence on how these individuals may be perceived in society. However, there is no research to date on their representation in mainstream media. Determining how and why people with amputations are presented to the audience is important to identify what psychosocial barriers are faced by these individuals and develop future interventions to minimize any potential negative societal associations to people with amputations.

This study will define the portrayal of those with limb loss in film and explore the variables in recent feature films released in America. Our hypothesis is that there will be a higher frequency of characters with amputations portrayed as major characters and in a positive manner.

METHOD

Procedures: We will use content analysis to identify various representations within the past five years.

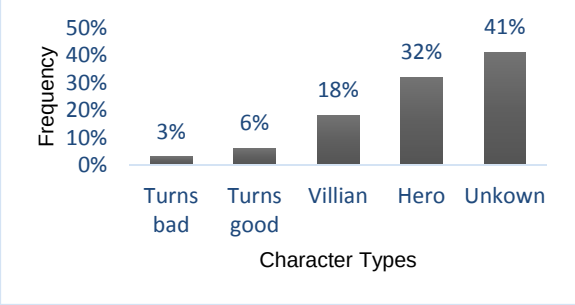
Search Strategy: Movies will be selected by searching the IMDB database for feature films released in theatres in the United States between years 2010 and 2015. Keywords featuring movie descriptors include: "amputee, prosthetic leg, prosthetic arm, prosthetic limb, artificial limb, artificial arm, artificial leg, mechanical arm, hook for hand, hook for a hand, wooden leg, and peg leg".

Data Analysis: The frequency with which a person with an amputation appears under a specific variable will be used to evaluate portrayal of people with amputations in the media. The variables include heroism, major or minor, amputation cause, and how realistic the prosthesis is.

RESULTS

The frequency with which people with ampuations appear as major characters, supporting, or minor characters are 37%, 17%, and 46%, respectfully. Many characters were unkown, but twice as many heroes as villians were portrayed in Figure 1. Most characters shown were wearing a prosthesis, 45% of which were wearing futuristic or bazarre prostheses such as the machine gun toting-zombie fighter, named Cherry Darling from *Planet Terror* or the bilateral blades used by the villian, Gazelle, in *Kingsman*. The frequency of trauma related amputations in Figure 2 is very high considering that most are due to dysvascular disease, which did not occur once in any of the films viewed.

Figure 1. Frequency of Villains and Heroes.



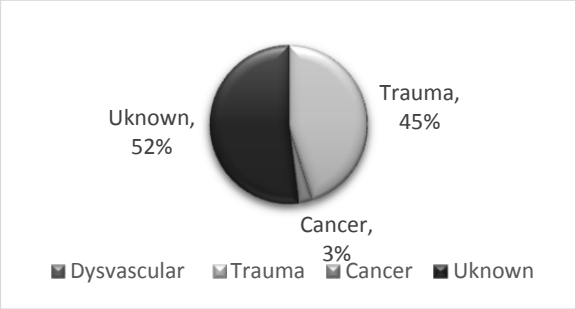


Figure 2. Frequency of Amputation Causes.

DISCUSSION

While the higher frequency of heroes over villains is promising in terms of positive portrayal, the unrealistic causes and prostheses could be considered negative if misunderstandings ensue. Further research should be done to investigate other media influences such as commercials and social media and the effects all of this has on the audience's perceptions and interactions with those missing limbs.

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FROM VILLAINS TO HEROES: A CONTENT ANALYSIS ON THE MEDIA PORTRAYAL OF PEOPLE WITH LIMB LOSS

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CONCLUSION

Popular feature films in the past five years show an unrealistic but positive representation of what living with an amputation entails. While the portrayal of heroes over villains is a good sign, there is still a lack of information being provided to the public.

CLINICAL APPLICATIONS

Negative stereotypes and unrealistic expectations could increase misunderstandings of what real people who are missing limbs have experienced. In addition people who have recently lost a limb could be unaware of the reality of their situation and how to cope.

Development of a low-cost clinical gait analysis system

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INTRODUCTION

In the P&O clinic, it can be useful to measure gait kinematics and kinetics to determine the outcome measures and effectiveness of treatment. A low-cost gait analysis system would allow higher reliability of quantitative assessment (Rathinam et al, 2012).

The objective of this study was to validate a Wii Balance Board (WBB) with an instrumented walkway, Kinovea free motion-tracking software, and video camera. We hypothesized this low-cost system would perform within a 5° angle and 5% force of a popular laboratory grade gold standard system.

METHOD

Subjects/Apparatus: One female, age 22, 55.9kg, 158cm tall; WBB, Kinovea software, GearPro camera, multi-camera Vicon motion analysis system, AMTI force plate

Procedures: Validation trials used a known angle and weights to compare the two systems. Ground reaction force (GRF), center of pressure (COP) and segment angles were collected on a test subject walking across the walkway multiple times (n=10).

Data Analysis: GRF, COP, and segment angle data from the laboratory grade system were analyzed using custom MATLAB software. Data from our low-cost system were analyzed using standard spreadsheet software (Excel). The percent error and absolute error metrics of the two systems were compared

RESULTS

During static validation trials, the WBB measured weights 2-3.7% heavier than the force plate. For all COP static tests, the maximum absolute position error was 0.48cm. The medial-lateral (ML) and anterior-posterior (AP) directions had average errors of 0.28cm. Kinematic trajectory data between the Kinovea and Vicon systems tracked closely (errors of 0.18cm AP and 0.28cm vertically). The human subject gait data showed similar trends between the force plate and WBB data (Figure 1). The COP data followed a similar trend, with an average COP_{AP} error of 0.95cm. The COP_{ML} position did not vary more than 5cm as is typical in gait. The average absolute errors for segment angles were 3.3°, 0.6°, 1.2° and 2.8° for the pelvis, thigh, shank, and foot, respectively. The pelvis and foot had the highest maximum error

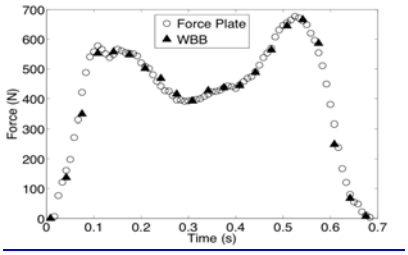

Figure 1. GRF of a representative step on the WBB and force plate

(11.8° and 7.4°, respectively).

DISCUSSION

The WBB measured peak GRF during gait within 5% of a laboratory grade force plate. The greatest errors in GRF data occurred where GRF values changed rapidly. The COP data were less accurate during dynamic tests but were consistent with previous studies (Bartlett et al, 2014) during static testing. The larger errors in GRF and COP suggest an inconsistent sampling rate of the WBB rather than inaccurate force measurements. The Kinovea/GearPro system measured segment angles within 5^{o} of the Vicon system for the shank and femur only. The higher pelvis and foot segment angle errors were likely due to placement of the ASIS and toe markers; contrast may have been the main issue Future directions are to ensure higher contrast between markers and surroundings, and perform trials on P&O patients.

CONCLUSION

Our system has potential to provide accurate quantitative gait analysis for under $300. It is possible for this system to be used with smart phone camera video. Low cost enhancements include a longer walkway and multiple WBB and cameras to capture more steps.

CLINICAL APPLICATIONS

This portable system can ~~be used to~~ aid in outcome measures and determining effectiveness of P&O devices without the need for a costly laboratory grade motion analysis system.

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Development of a low-cost clinical gait analysis system

M. Emily Littrell, Young-Hui Chang, Brian P. Selgrade

Comparative Neuromechanics Laboratory, School of Applied Physiology, Georgia Institute of Technology

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EFFICACY OF A PROSTHETIST-CENTERED PROGRAM TO ASSESS AND ADDRESS EMOTIONAL WELL-BEING OF INDIVIDUALS WITH LIMB LOSS

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INTRODUCTION

Individuals with limb loss have higher risk for depressive symptoms and other forms of psychological distress (Darnall et al., 2005, Coffey et al., 2009). Higher levels of psychological distress have been shown to adversely affect the rehabilitation process and outcomes (Asano et al., 2008, Wegener et al., 2009). Data indicate that a large percentage of persons with significant depressive symptoms, report needing mental health service but not receiving them (Darnell et al 2005).

Traditionally the mental health needs of people with limb loss were seen as the responsibility of psychologists, social workers or the primary physician. However, comprehensive care of the individual is a team responsibility including prosthetists and the person with limb loss (Wegener et al., 2008). Prosthetists have ongoing relationships with amputees and are positioned to educate patients regarding the signs of psychosocial distress and provide information on resources for patients to seek appropriate care. However, prosthetists currently are not prepared to take on this task effectively. We conducted a multi-site study to determine the efficacy of a prosthetist-centered program to assess and address emotional well-being of individuals with limb loss.

METHOD

Patients were recruited at six study locations. Study locations were divided into control and intervention groups. Control sites provided patients with usual care and educational materials (*inMotion* Magazine and other publications) Intervention sites provided patients with usual care and engaged patients with Improving Emotional Well-being Program materials, consisting of a validated tool to assess depressive symptomology and satisfaction with life and a brochure listing local resources, including mental health providers and amputee support groups.

Procedures: Patients at study locations who met inclusion criteria were invited to participate in the study: English speaking patients with a major amputation requiring prosthetic services and are 18 years or older were invited to participate in the program. Participants completed a questionnaire at study enrollment and 3-month follow-up. Participant outcomes were: Depressive symptoms, Satisfaction with life, Self-efficacy, Utilization of Resources, Program Satisfaction, and Satisfaction with Overall Care. Prosthetists also completed a questionnaire at start of the study and 3 months post-study. Provider outcomes: provider satisfaction with care provided, confidence in managing psychosocial factors related to prosthetic care.

Data Analysis: Outcome data for patient participants analyzed using hierarchical regression models to account for covariates. Provider outcomes analyzed using non-parametric statistics to detect group differences.

RESULTS

Participants: N=101 (Mean Age = 57; 72% Male, 63% white, 30 % African-American, 7% Other; 4% Hispanic; 45% Married; 27% High School, 33% College Education; 52% dysvascular, 40% trauma, 7% Cancer). Data collection is concluding with a 87% follow up rate. We report estimates of treatment effects for patient and provider outcomes along with 95% confidence intervals.

DISCUSSION &CONCLUSION

The Improving Emotional Well-being Program has been developed to provide prosthetists with the tools and resources to help improve the emotional well-being of people with limb loss.

CLINICAL APPLICATIONS

The program is feasible within outpatient clinical setting and is well received by patients. The IWBP is available through the Amputee Coalition. Online training will be available soon .

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VALIDITY ASSESSMENT OF THE IPHONE 5S AS A PEDOMETER FOR ABLE-BODIED PERSONS

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INTRODUCTION

The health benefits of physical activity, such as reducing risk of cardiovascular disease and mortality (U.S Surgeon General, 1996), are well documented. Step count is a useful proxy measure of physical activity during daily living (Tudor-Locke, 2004) and can be easily measured using low-cost pedometers. Given the popularity of the iPhone (Apple, Cupertino, CA) and its built-in accelerometer system, this device provides a convenient and universal platform to count steps during daily activity for a sizable percentage of the global population. Apple recently standardized the accelerometer hardware-software platform in the iPhone 5S to eliminate reliance on custom pedometer applications and the recurring need for validation assessment of these algorithms. The purpose of this study was to assess the concurrent validity of the iPhone 5S pedometer and the relationship between its measurement error and walking speed.

METHOD

Subjects: A convenience sample of 20 able-bodied persons (10 male, 10 female, 28±5 years, 1.71±0.14 m, 74.8±21.2 kg) participated in this study.

Apparatus: iPhone step count was compared against steps recorded by manual count and the StepWatch™ activity monitor (Orthocare Innovations, WA), which represented the criterion standard clinical measure.

Procedures: The StepWatch was programmed for each subject and attached to the right lateral malleolus as per manufacturer recommendations. The iPhone was stored in the subjects' right hip pocket. Both devices were activated and the subjects then walked a 30m straight-line path in a level carpeted hallway at slow, normal, and fast walking speeds.

Data Analysis: Concurrent validity of the iPhone as a pedometer was assessed with Spearman's correlation (ρ) analyses between measurement of the iPhone and both the manual count and StepWatch. Bland-Altman analyses were used to assess agreement between outcomes of each instrument and the presence of a fixed or proportional bias. Fixed bias was evaluated using a one-sample t-test to determine if the mean error between measures was different than zero. Proportional bias was evaluated using Spearman's analyses to determine if error between measures was related to the total number of steps. A best-fit polynomial was used to model the relationship between the iPhone to manual count absolute error and walking speed. The critical α was set at 0.05.

RESULTS

The average slow, normal, and fast walking speeds were 0.95±0.13 m/s, 1.33±0.14 m/s, and 1.77±0.24 m/s, respectively. The iPhone step count was strongly correlated to the manual and StepWatch count for only the fast walking speed ($\rho \geq 0.733$, $p < 0.001$) and no fixed or proportional bias was present for this condition. For the slow walking speed, the iPhone underestimated step count by an average of 8 steps, or 16% ($p \leq 0.029$), and a strong correlation between total number of steps and error ($\rho \geq -0.633$, $p \leq .003$) was observed. The relationship between iPhone to manual count error and walking speed was accurately described by a negative power function (Figure 1).

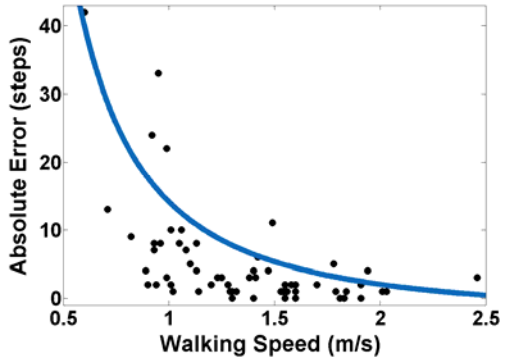

Figure 1. iPhone error versus walking speed. The curved line represents the best-fit model (r^2=0.59) of these data.

DISCUSSION

The iPhone accurately counted steps for only the fast walking speed condition. This result was supported by the observed relationship between error and walking speed where measurement error increased exponentially at slower speeds and approached zero at faster speeds. The iPhone had a consistent error for slow walking speeds and this inaccuracy reached up to 78% in this study. These mixed results suggest promise for the iPhone to serve as a valid pedometer, but reveal important limitations with real-world implications for use in individuals that walk slowly.

CONCLUSION

Despite improvements to the iPhone system through hardware-software standardization, additional work is needed to improve its accuracy across walking speeds before being considered a valid pedometer.

CLINICAL APPLICATIONS

The current iPhone 5S pedometer is accurate for monitoring daily physical activity via step count of individuals with faster walking speeds but may not be valid for patient groups that walk slowly.

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American Academy of Orthotists & Prosthetists
42nd Academy Annual Meeting &
Scientific Symposium
March 9 – 12, 2016

FPTH14

The Benefits to Orthotic & Prosthetic Practitioners of Using Good Patient/Practitioner Communication

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INTRODUCTION

Medical research reveals good communication between doctors and patients is an important element of health care.[1,2] Furthermore, medical research indicates numerous, common problems related to communication that adversely affect patient outcomes. Good communication is essential to the provision of quality care and treatment to patients and has numerous benefits for patients and healthcare providers.[2,3]

However, similar research does not exist in orthotics and prosthetics (O&P). Hence, this literature review had two specific aims: (1) to identify benefits to medical providers of good patient/practitioner communication, and (2) consider these benefits within the context of a typical orthotic and/or prosthetic patient encounter and summarize potential beneficial themes of good communication for O&P practitioners.

METHOD

A literature search was performed using PubMed, Ovid Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Google Scholar. A table was used to extract, organize and categorize the benefits to the medical provider found in each article.

RESULTS

A total of 71 articles were included in this literature review, yielding 17 benefits to medical practitioners of using good patient/practitioner communication. From these, six beneficial themes were summarized that are hypothesized to relate to O&P clinical practice (Table 1).

Table 1 Hypothesized beneficial themes for O&P derived from literature describing benefits to the medical practitioner of using good communication.

Beneficial Themes to O&P	Benefits to Medical Practitioners	# articles benefits were mentioned
Lessens the Risk of Litigation	Lessens the Risk of Litigation	25
	Increases Trust in the Physician	15
Makes Efficient & Effective Use of Appointment Time	More Information is Gathered from Patients	18
	Saves Time/Does Not Require More Time	12
	Possible to Resolve All Presenting Issues	6
	Patients Require Fewer Return Visits	2
Improves Patient's Outcomes	Increases Patient Adherence to Treatment Guidelines	40
	Improves Patient Outcomes	38
	Improves Patient Recall of Visit Information	4
	Manages Patient Expectations	3
Improves Patient Satisfaction & Increases Referrals	Patient Satisfaction Increases	44
	Retains Patients	14
	Patients Refer Family & Friends	3
Improves Practitioner Job Satisfaction	Increases Job Satisfaction for Doctors	18
	Improved Personal Well-Being for Doctors	8
	Increases Professional Respect	1
	Fewer Patients are Viewed as Unreasonable	4

DISCUSSION

The benefits from other medical disciplines were not necessarily exclusive to one of the six beneficial themes. However, for clarity each benefit was listed as part of only one beneficial theme. An additional benefit specific to O&P practitioners is that good communication facilitates adherence to the American Board of Certification (ABC) Scope of Practice & Code of Professional Responsibility. This review may be used to identify areas of further research, including the need to develop ways to analyze individual practitioner communication skills to identify areas needing improvement and the development of best practices for good communication in O&P.

CONCLUSION

There are several benefits to medical providers that are relevant to orthotists and prosthetists with regards to using good communication in patient encounters. These benefits may have a positive impact on orthotists and prosthetists, their practice, and their patients.

CLINICAL APPLICATIONS

This review should motivate orthotic and prosthetic practitioners to use good communication in clinical encounters with patients.

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March 9 – 12, 2016

"Survey of the Effectiveness of Preamputation consultations In a large teaching hospital in the UK"

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INTRODUCTION

Amputation surgery is a life changing event in the life of a patient. Only a small number of patients are referred prior to amputation and the vast majority are those who have had many unsuccessful attempts at limb salvage and contemplate this ablative surgery as an option to return to an active life style. The other group are complex vascular cases or patients with neurological or developmental anomalies. This service provides an opportunity to the patients and their families to gather information from the medical rehabilitation team regarding various aspects of amputation so that they can make an informed choice. It also helps them prepare for their physical and social environment post amputation.

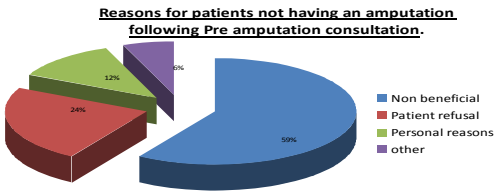
METHOD

The data was collected from medical records and patients who attended between Jan 2008 and Feb 2010 were included. In total 45 patients selected. A questionnaire was designed and sent to 40 patients. The questionnaire gave a quantitative data and a qualitative analysis from this survey replies as well as patients' medical notes was taken for triangulation with the quantitative data. Number of patients returning their completed questionnaire was 23 out of 40. In this study 78% of the patients were males and 22% were females. Patients' age ranged from 20-60 years. Causes of amputation were: 24% had chronic osteomyelitis following long standing trauma, 27%, vascular, 31% due to chronic severe pain. 60% of the total patients had transtibial amputation, 30% had transfemoral and 10% were in other categories.

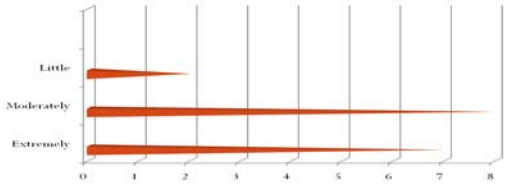
The data was analysed by a simple calculation and no statistical tests were employed.

RESULTS

81% of the patients replied that the consultation met with their expectations. 75% of the patients expressed that their concerns were addressed during the consultation. Only 50% of the patients reported that they were made aware of the process of rehabilitation including the time scales. Only 44% of the patients were provided with the information about the team members who would be involved in their rehabilitation programme. 88% of the patients replied that they had made an informed decision about the treatment i.e. amputation after the consultation. Only 69% of the patients claimed that they understood the complications associated with amputation.



Was the consultation effective and useful?



DISCUSSION

In this cohort it was interesting to see that 60% of the patients referred by various Consultants, like Orthopaedic and Plastic Surgeons were having chronic severe pain following major trauma. This indicates that patients suffer for a long time with pain before offering themselves or making up their mind to have an amputation. Another interesting and unexpected observation was that 59% of patients were advised that amputation would not be beneficial with regard to their symptom and mobility management. There is very little in the literature regarding the effectiveness or indeed practice of pre-amputation consultation.

CONCLUSION

This survey shows that pre-amputation consultation is a useful and effective service although it is relatively time consuming. The consultation affected decision making in 62% of patients. The majority of patients were satisfied with the consultation.

CLINICAL APPLICATIONS

The survey highlights the following points: pre-amputation consultation should be offered to most patients undergoing planned amputation and also to emergency operations wherever possible. Pre-amputation consultation has a positive impact on the patients rehabilitation programme and in the adjustment to their new environment.

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A Functional Comparison of a Carbon Fiber AFO and Two Modular KAFO Conditions Using Outcome Measures

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INTRODUCTION

An increasing population requiring orthotic treatment is the group of patients who have suffered traumatic brain injuries (TBI) and spinal cord injuries (SCI). This increase is pronounced in the Veteran's Health Administration system, as prevalent conditions of participants in operations Enduring Freedom, Iraqi Freedom, and New Dawn requiring care are TBI and SCI. This population presents a challenge to orthotists as these patients can have a broad spectrum of clinical presentations. There is a unique subset of these individuals who are young and otherwise healthy, wish to maintain highly-active lifestyles, and are able to rapidly progress through rehabilitation and reintegration.

There are several orthotic interventions used to meet the requirements of these patients who present with lower extremity weakness. One such intervention is the modular, carbon-fiber knee-ankle-foot orthosis (KAFO). That is, a KAFO that can also be separated to function as an ankle-foot orthosis (AFO) or knee orthosis (KO). There is limited research to support the effectiveness of these devices, however, and questions persist in the orthotic community as to what patient populations would actually benefit from the use of these devices.

The purpose of this study is to determine the clinical efficacy of a modular, carbon fiber KAFO, and its KO option, compared to a high-activity AFO using clinically-implementable outcome measures. The study documents the device usage of a young TBI patient through his rehabilitation process.

METHOD

Outcome measures utilized in the testing were the timed up & go (TUG), 10-meter walk test (10mWT), and 2-minute walk test (2MWT) with rate of perceived exertion (RPE). The patient completed 2 trials of the TUG at a comfortable walking speed with the lower time being recorded. The patient completed 3 trials of the 10mWT at a comfortable pace and 1 trial as fast as possible. The average comfortable pace and fastest pace were recorded. The subject completed 1 trial of the 2MWT with total distance being recorded. RPE was taken immediately following the 2MWT. This protocol was repeated for each condition.

The patient completed the testing protocol at initial evaluation with no orthosis (NO) to establish a reference. The patient was then fit with a custom Trulife Combo KAFO as part of his transitional rehabilitation program. During fabrication of this orthosis he was fit with a pre-fabricated Streifeneder PeroSupport.tec AFO. Later in his rehabilitation process he began wearing only the KO portion of the combo KAFO with boots. The patient was given a one-week accommodation period to each orthosis and then completed testing. Clinical information on the patient including LE MMT scores were recorded from PT notes in his chart.

RESULTS

The results from outcome measures are shown in figure 1. Signficiant findings are as follows: For the 10mWT the KAFO showed the highest normal speed and fastest possible speed. The AFO was higher than NB and KO for fastest speed. 2mWT distance was greatest in KAFO compared to NB and KO. All orthosis conditions required less effort than did NB. The patient showed improvement in some LE MMT scores from intake to discharge.

OM	NB	AFO	KAFO	KO
10mWT	1.17m/s	1.10m/s	1.35m/s	1.14m/s
Fast	1.53m/s	1.88m/s	2.09m/s	1.47m/s
TUG	8.66sec	7.90sec	6.65sec	7.41sec
2MWT	410ft	450ft	490ft	430ft
RPE	7	3	2	2

Figure 1. Outcome measure results per orthosis

DISCUSSION

The modular KAFO showed the highest functional result across all measures. The AFO condition also showed potential for increased functional capacity compared to the KO condition. The KO, however increased perceived function similarly to the KAFO and AFO. It should also be noted that the KO condition is the current intervention most utilized by the patient in his daily life. The patient subjectively noted that turns were easiest with the KO condition, which may contribute to his preference for that option.

CONCLUSION

The modular, carbon fiber KAFO was the most effective orthotic intervention for this patient. The independent KO portion was also effectively used by this active patient progressing through rehabilitation.

CLINICAL APPLICATIONS

The modular KAFO shows potential to be an effective intervention for active patients with foot-drop and genu recurvatum. The KO portion may be a viable option of that orthosis for these patients to increase function and decrease exertion in some situations.

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"ABC Univeristy1, DE Hospital2 (click here to type author affiliations, affiliation style)"

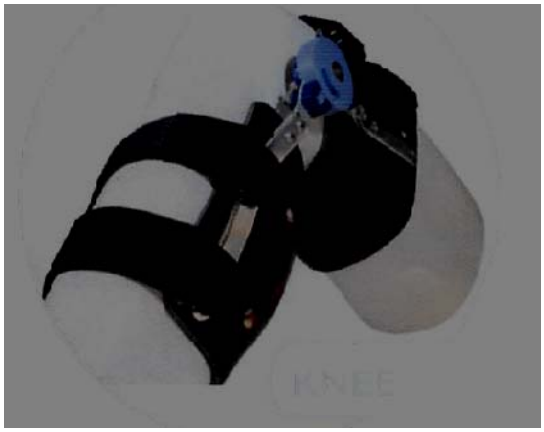
INTRODUCTION

Contracture management has been one of the more difficult challenges we face as orthotists. Ensuring optimum results for our patients in order to prevent surgery or regain the biomechanics for standing and ambulating are what we strive for and quite frankly, are what is expected of us. But how do we get such results? What are the key factors necessary in order to provide the best possible outcome for our patients? This case study will focus on using dynamic splinting for contracture management, its results, and discuss the essential factors needed for success.

METHOD

In this case study, a custom dynamic knee extension assist orthosis was used with having lateral dynamic concentric extension knee joints and medial free motion knee joints, polypropylene thigh and calf cuffs to distribute the force, and an anterior knee cap to create a three point force (see figure 1 below). This custom knee orthosis was used during night-time hours to provide a low stretch over a long period of time in order to gain the optimum results while measuring ROM weekly to ensure ROM increase is attained. Once ROM has plateaued then the tension is increased. In this case study, patient suffered incomplete spinal cord injury due to MVA in 2013. The goal of the patient was to ambulate once again but since the accident had developed a -25 degree knee extension contracture in his right lower extremity. With the assistance of the physical therapist, we were able to provide patient with the dynamic knee extension orthosis and monitor his progress on a weekly basis recording the results.

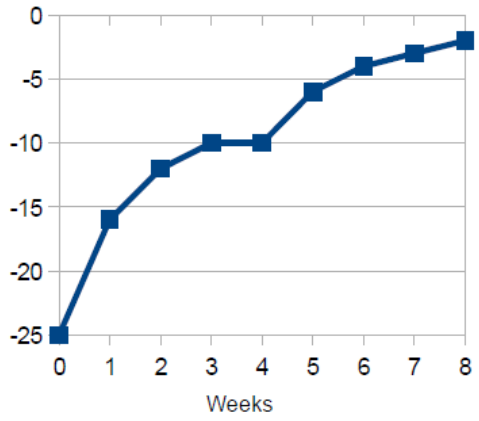
Figure 1. Sample of Custom KO



RESULTS

Results were recorded on a weekly basis during the patient's therapy session by the physical therapist. It was observed that the best results came the week preceding a tension increase, with the greatest overall increase occurring during the initial first week of treatment (see
figure

Figure 2. Knee Extension ROM



DISCUSSION

After conducting this case study it is evident that dynamic splinting for contracture management is a viable treatment. However, we face several challenges in order to achieve desired results such as compliance and proper follow up, even knowing when to provide such orthosis. The intention of this abstract is to instill confidence and knowledge to other orthotists to ensure they have the best chance to achieve results as the patient in the case study received. This abstract will discuss the design and fit of the dynamic stretch orthosis, the tension settings and follow up, and lastly the appropriate diagnosis and contra-indications.
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THE EFFECT OF AFO OPTIMIZATION ON BIOMECHANICAL VARIABLES TREATING NEUROMUSCULAR CONDITIONS

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INTRODUCTION

Research demonstrates that ankle foot orthosis stiffness can influence biomechanical variables in the treatment of some pathologic neuromuscular conditions (Kobayashi, 2011, 2013). Studies have recommended a variety of stiffnesses to compensate for the biomechanical deficits at the ankle and knee associated with these conditions (Wong, 2009). The clinical optimization of ankle foot orthosis mechanical characteristics is an iterative, and highly individualized process. Optimal mechanical characteristics, and the path to orthotic optimization may be influenced by the pattern of biomechanical deficits. In this pilot study, the effect of ankle foot orthosis mechanical characteristics on biomechanical variables is measured and evaluated in the context of biomechanical deficits and a standardized adjustment procedure as a path to orthotic optimization.

METHOD

Subjects: Subjects included in this study were diagnosed with multiple sclerosis or stroke. All subjects were ambulatory with unilateral weakness or hypertonicity of the ankle and knee. The orthoses worn by subjects were custom, double upright ankle foot orthoses with Triple Action™ ankle joints. The orthoses were rigid carbon composite to isolate control of sagittal stiffness and ankle alignment to the ankle joints.

Apparatus: An eight camera Vicon motion analysis system was used to measure biomechanical variables. Motion data were captured from both lower extremities.

Procedures: Kinematic measurements were made with subjects in quiet standing, and walking on a level treadmill. Triple Action™ ankle joints were used to facilitate the independent adjustment of plantarflexion torque, dorsiflexion torque, range of motion, and null torque ankle alignment. The default, clinically optimized ankle joint settings were determined using a standardized adjustment procedure. During motion trials, ankle joint settings were independently adjusted to change the orthosis mechanical characteristics with non-adjusted settings fixed at their default values.

Data Analysis: Motion data were pre-processed to automate and objectively identify events through the gait cycle for kinematic measurements. Events during quiet standing, terminal swing, early and late stance phases of gait were analyzed to compare normative values, rates of change, and standard deviation.

RESULTS

Using the standardized adjustment procedure, clinicians independently arrived at similar optimized ankle joint settings. In static weight bearing, the ankle joint alignment setting at maximum torque correlated to changes in ankle and knee flexion angles for subjects with motor insufficiency. In gait trials, changes in null torque alignment towards dorsiflexion correlated with increased foot to floor contact angle for subjects with motor insufficiency at initial contact. For subjects with hypertonicity, initial contact foot to floor angle was less reliably correlated to null torque alignment. Decreased plantarflexion resist significantly correlated with increased plantarflexion excursion in terminal swing for subjects with hypertonicity. In late stance, decreased plantarflexion resist correlated with increased knee extension for subjects with motor insufficiency. For subjects with hypertonicity, decreased dorsiflexion resist correlated with decreased knee extension.

DISCUSSION

Motion data from this pilot study suggest that correlations exist between AFO mechanical characteristics and biomechanical variables. In some cases the orthotic influence was predictable, but appeared to be significantly effected by the pattern of biomechanical deficits. The influence of null torque alignment was more predictable under higher torque conditions. The standardized adjustment procedure was useful in determining default component settings as a basis for comparison.

CONCLUSION

Though AFO mechanical characteristics were shown in some cases to predictably influence biomechanical variables, further research is necessary to establish a broader correlation, and a standardized adjustment procedure to clarify the path to orthotic optimization.

CLINICAL APPLICATIONS

The orthotic treatment of lower extremity biomechanical deficits is an important area of orthotics. An improved understanding of the optimization process is necessary to help improve clinical outcomes.

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FPTH14

IMPROVEMENTS IN WALKING PERFORMANCE WHEN USING A POWERED ANKLE PROSTHESIS

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INTRODUCTION

Powered ankle prostheses show promise in increasing preferred walking speed, and reducing energetic cost and some gait asymmetries in persons with transtibial amputations (Herr and Grabowski 2012, Ferris 2013). Successful translation of these benefits from lab to clinic may depend on the ability of prosthetist to replicate the device tuning procedure. It is unknown whether a powered ankle prosthesis with a typical clinical tuning would produce similar improvements in walking performance as those demonstrated in laboratory studies. Therefore, the purpose of this study was to characterize improvements in level walking performance for people using a powered ankle prosthesis that was tuned to approximate the work of an intact human ankle.

METHOD

Subjects: Five (5) males (age 49 ± 12 yrs, BMI 27.8 ± 4.2 kg/m^2, K3+ functional levels) with unilateral traumatic transtibial amputations and 5 age-matched healthy controls participated in this study. Two participants were regular users of the powered prosthesis. The remaining participants were fitted with the BiOM ankle (BiOM, Inc. Bedford, MA) by a manufacturer-certified prosthetist, who matched prosthetic ankle work to that of the average intact human ankle over a range of speeds. At least 30 minutes of accommodation was given prior to testing.

Procedures & Data Analysis: Participants used the BiOM and their own dynamic response prosthesis (DR). Preferred walking speed was measured during overground walking. Metabolic cost of transport (COT) was measured during a 3-minute fixed-speed treadmill walking trial.

RESULTS

Participants' preferred walking speed increased by 4.8% when using the BiOM (+0.06 ± 0.06 m/s). Three participants had decreased COT when using the BiOM (-0.027 ± 0.023 J/N·m) **(Fig. 1)** while the remaining 2 increased (+0.024 ± 0.006 J/N·m). There were no significant differences in stride length or temporal-spatial symmetry ($p > 0.084$).

DISCUSSION

The modest gains in preferred walking speed and energy expenditure in the present study compared with previous work may depend on both the tuning of the device's power delivery parameters as well as the functional level of users. The 10 available tuning parameters allow for a potentially complex tuning by clinicians with extensive training and device experience and may explain the discrepancy in results compared to Herr and Grabowski (2012). The participants in Ferris et al. (2013) were active-duty military personnel and likely higher-functioning than the population sampled in the present study, which may explain the improvements in step symmetry not replicated here. Development of an iterative, repeatable tuning algorithm may improve the translation of benefits to users. Assessments of traversing slopes and varied terrain may also reveal clinically meaningful benefits in walking performance.

CONCLUSION

When tuned by a certified prosthetist in accordance with manufacturer recommendations, the powered ankle prosthesis prompted only modest improvements in walking performance compared to previous studies.

CLINICAL APPLICATIONS

These results highlight the important role that tuning of powered devices may play in delivering proposed benefits to users. The benefits of powered devices may also depend on the functional status of users.

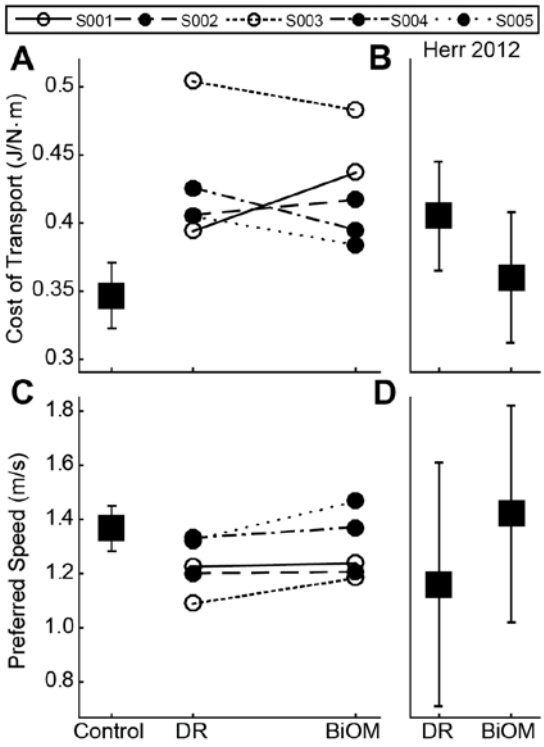

Figure 1. Average COT (A) and preferred walking speed (C) in DR and BiOM ankle prosthesis. Data from control subjects and from (Herr 2012) (B, D) are shown for comparison. Error bars represent ±1 SD. 'O' indicates regular BiOM users.

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A METRIC TO QUANTIFY THE "DEAD SPOT" PHENOMENON IN PROSTHETIC FEET

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INTRODUCTION

The "dead spot" phenomenon (DSP) is a period of limited motion during the stance phase of amputee gait during which the prosthetic foot is neither yielding nor returning energy to the user. Amputees describe this phenomenon as a "flat spot" or "stall" in the foot and as a feeling of having to "climb over the prosthetic foot."[1,2] The occurrence of the DSP is clinically significant as it requires the amputee to produce additional force to resume progression of the foot through stance which can result in an inefficient, compensatory gait pattern. This increased ambulatory energy requirement can reduce walking speed, stability, and activity.[3]

Some prosthetic manufacturers claim the DSP is absent or minimized with use of their feet, however, the DSP has not yet been clearly identified kinetically making it difficult to make such a determination. Correspondingly, a definitive metric to quantify the DSP needs to be developed..

METHOD

Center of pressure (CoP) is used to quantify motion in the prosthetic foot. Rate of change (RoC) is calculated and an ideal mean is found by dividing the length of the foot by the stance time for each individual step. A threshold value is then calculated to isolate DSP data by multiplying the mean RoC by a constant coefficient of 0.60. Data within 10-50% stance phase is analyzed to determined DSP. Data before this timeframe is excluded due to confounding of double stance and data after is excluded as it is specific to action of the toe lever. The metric developed and used here compares RoC data to the threshold value to determine DSP time, DSP magnitude, and total DSP area.

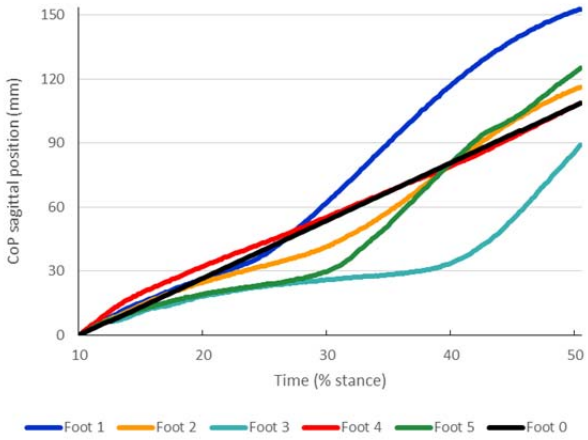
The study utilized a randomized, double-blinded, repeated-measures design. Four amputees (2 TT, 2 TF) were tested on 5 foot conditions by an 8-camera Vicon system with 2 AMTI force plates. A 2-way ANOVA was used to compare conditions and a 1-way ANOVA was used to compare feet to a hypothetical ideal condition with no DSP. The level of significance was set at $p<0.05$.

RESULTS

DSP time was lowest in feet 1 and 4 and highest in foot 3. DSP Magnitude was lowest in foot 3 with all other feet being similar. DSP area was lowest in foot 4 and highest in foot 1. No value was found to be similar to the ideal condition in the primary analysis.

An *ad hoc* analysis of metric values was performed by subject and 18 metric values were found similar to the ideal condition. 17 occurred in TT subjects. Foot 1 and 4 accounted for 10 of 18 (55.6%).

Figure 1. CoP slopes for all foot conditions vs. ideal. Prolonged plateaus indicate the dead spot.



DISCUSSION

A favorable trend in DSP metric values was found in feet that utilize continuous plantar rockers as a design element. These feet had no detectable DSP when tested on the TT subjects. Only 1 of 18 findings of similarity to the ideal condition was found in TF subjects, indicating that further research is needed to determine if this metric can be implemented in TF subjects in its current form.

CONCLUSION

A viable methodology to quantify the dead spot phenomenon in prosthetic feet was developed and implemented. The results of this work found that continuous-lever prosthetic feet had the smallest dead spot and that different calculations may be needed between subjects of differing amputation level.

CLINICAL APPLICATIONS

This work allows the dead spot to be evaluated in an objective way which may guide future prosthetic foot design and prescription guidelines.

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Volume Management with a Twist

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Click Medical

INTRODUCTION

Regardless of etiology or level of amputation the residual limb undergoes substantial change in shape and volume up to 18 months after amputation with continued fluctuation throughout the lifetime of the amputee (Sanders, 2011). Constant and continual changes in residual limb shape and volume lead to problems in creating and maintaining an accurate fit of a prosthetic socket necessary for skin protection and maximal functional control of the prosthesis. Nearly 2 million persons are living with the limb loss in the United States (Zeigler-Graham, 2008). Most amputees utilize socks and/or have multiple adjustments or replacement sockets in order to maintain fit and function

METHOD

A systematic review of measurement and management of residual limb volume change by Sanders and Fatone (2011) verified the presence of significant volume and shape change of the residual limb within the first 18 months post amputation and continued changes within the mature residual limb. This review also reported designs and challenges to accommodate volume changes with adjustable sockets utilizing adjustable bladders or strap tension.

Traditional solutions for accommodating volume change address the problem with a residuum global solution or a more localized solution. The patient can vary the global volume of the residual limb by either adding or removing sock ply. This method requires removing the socket to adjust sock ply, Zachariah et al (2004) reported that when the socket is removed residuum volume increases up to 11% typically within the first 8 minutes after socket removal, thereby creating variation and unpredictability in volume management. This method does not address localized volume changes within the residuum and could cause excessive pressure over tissue that has not changed, such as tissue over bony prominences. Other solutions involve the modification of the in-socket shape and volume by selectively adding padding. The method of adding padding may more appropriately address regional volume or shape changes however the padding may compress over time and does not accommodate diurnal changes. When the residual limb has had significant change that cannot be accommodated a new socket is manufactured.

Prolonging the life of a socket without compromising the fit and function of the socket can be valuable to the patient and the prosthetist by reducing inconsistency managing volume fluctuations with sock ply and delays in responding to volume changes when a prosthetist is required to provide socket adjustments.

We propose adding an amputee adjustable non-elastic closure system to a custom socket designed with compressible panels. A customizable light weight, low profile closure/compression system with a non-slip mechanical reel, steel lace and nylon guides allows the patient to make infinite micro adjustments, by twisting a knob, to modify the socket fit without removing the socket. The custom design of the socket and panels provides global and/or localized compression of the socket around the residual limb. Thereby, transferring torque load from the user to the socket and the prosthesis for increased functional control. The closure system could be used for any level of amputation on immediate post-operative rigid, prepatory or definitive sockets.

Additionally this system can be utilized to aid in donning and doffing and create adjustable suspension designs all with a single handed operation that requires minimal force.

RESULTS

We have manufactured and successfully fit socket designs utilizing the adjustable mechanical closure system to accommodate volume fluctuations.

Custom Panels with Adjustable Closure for Volume Management

DISCUSSION

Further investigation is required to quantify the volume accommodation in a designed socket and to measure torque output with an adjustable socket.

CLINICAL APPLICATIONS

A custom amputee adjustable socket is of value to patient and prosthetist in order to provide immediate accurate socket fit and maximal functional control of the prosthesis. This closure system can also be used in orthotic applications where simple adjustable closure is indicated.

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Functional Electrical Stimulation for Patients With Parkinson's Disease, A Case Study

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INTRODUCTION

Parkinson's Disease (PD) is a neurodegenerative brain disorder that affects over 1 million people in the United States alone. As the disease progresses, patients exhibit short stride length, slow, shuffling gait, and a stooped posture. Motor-cognitive demands also increase (Fritz, 2015) and dual tasks such as walking while talking become difficult. Bradykinesia and postural instability negatively affect ambulation.

Physical activity tends to decline with disease progression (Cavanaugh, 2012), but moderate-to-vigorous exercise during the mid-stages of progression may slow the rate of functional decline (Goodwin, 2008).

Functional Electrical Stimulation (FES) via the WalkAide® FES System (WA) stimulates the peroneal nerve to activate the dorsiflexor muscles, decrease muscle atrophy, and improve voluntary motor control. Use of the WA has been shown to improve gait speed, perceived walking ability, and quality of life for patients with other neurologic disorders (Mayer 2014) but little literature can be found to address the use of FES in PD.

The object of this single case study is to document the effects of FES on the gait and quality of life of one such patient .

METHOD

Subject: A 63 year old male with PD diagnosed 6 years prior to this study and no other comorbidities.

Apparatus: ROM, MMT, 6 Minute Walk Test, TUG Test, Timed 10-Meter Walk Test, OPUS Functional Status Measure, OPUS Health Quality of Life Index, Neuro-QOL Fatigue Survey

Procedures: Subject was evaluated by clinician for ROM and MMT, completed walking tests with no assistive devices, and completed surveys. Subject was then fitted with the WA and used it for 2 months with appropriate follow-up care and adjustment.

2 months after initial fitting, subject was re-evaluated with ROM & MMT, completed all walking tests using the WA, and completed the surveys.

Data Analysis: Walking was quantified using speed. Impact on the subject's ADLs and QOL was quantified by the various surveys.

RESULTS

At the initial evaluation, all ROM was WNL as was the right leg MMT. The left leg showed knee flexion and extension as 4/5, ankle plantarflexion 4/5, and ankle dorsiflexion 3/5. At the 2 month evaluation, all ROM and MMT were WNL.

The subject showed improvement on all measures of walking speed, as shown in Table 1.

	BEFORE WA	AFTER 2 MONTHS WITH WA
6 MWT	201.2 m	448.1 m
TUG	14.1 s	10.7 s
10 MWT	0.7 m/s	1.3 m/s

Table 1. Changes in gait speed

On the various surveys, the subject reported improvement in ability to ambulate on varied terrain and a decrease in fatigue.

The subject also reported perceptions of having better balance, feeling that he walked with a more normal, upright posture, being able to ambulate without having to look at or concentrate on his feet, and having much better endurance after 2 months of using the WA. He stated that he notices these improvements even when he is not wearing the device. He was observed to be more able to maintain a conversation while walking at the 2 month evaluation.

DISCUSSION

The data indicate a strong clinical benefit of the WA for this patient. The improvement in gait speed and decrease in fatigue indicate that the WA enables the subject to maintain a vigorous level of physical activity, which positively impacts his quality of life and may slow the progression of some of his symptoms. The subject also expressed a high level of satisfaction with the device. He continues to use the WA at this time to improve the longevity of this case study. Further research with a much larger cohort should be pursued.

CONCLUSION

The improvements noted in gait and patient perception show the WA to be an excellent therapy for this particular patient, and encourage further study to include PD as one which is routinely treated with FES.

CLINICAL APPLICATIONS

FES shows promise as a clinically applicable therapy for patients with PD, with potential to improve a user's mobility, safety, and quality of life.

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IDENTIFYING TRAINING STRATEGIES FOR PROGRESSING EXOSKELETON USERS TOWARDS EVERYDAY FUNCTIONAL AMBULATION

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INTRODUCTION

The ReWalk is a robotic exoskeleton designed to allow people with paralysis due to spinal cord injury (SCI) to stand and walk. Previous studies have shown that the ReWalk is safe for level ground ambulation in a clinical setting with supervision (Zeilig 2012; Esquinazi 2012), however research has not yet examined the potential for community use. In our study we hypothesize that we would be able to train subjects with SCI to use the ReWalk to perform over ground walking, and curb, ramp, and stair negotiation with close supervision in a safe manner within 36 session.

METHOD

A total of 45 Subjects were screened in the lab, with 17 passing the screen and 7 subjects completing training. The subjects range in ASIA level from T4-T11, all A or B. Subjects received 18 training sessions with a pretest and posttest. Some went on to receive an additional 18 sessions and post test for a total of 36 sessions. The decision to continue on for addition sessions was based on their preference as well as their potential to meet study goals. Outcome measures included the 10 meter walk test, 6 minute walk test, stopping at targets and on command, and functional mobility on stairs, ramps, and curbs.

RESULTS

ReWalk has set out a list of competancies for home use that require a patient to ambulate at least 110 m in the 6 minute walk test. Additionally patients must be able to walk at a speed of .4 m/s in the 10 meter walk test. Below you can see a graph of each of our subjects scores on these tests at 18 session and at 36 if they went on to train to 36.

Sub.	6MWT-18 (m)	6MWT-36 (m)	10MWT-18 (m/s)	10MWT 36 (m/s)
2	67.11		0.35	
8	57.63		0.11	
9	59.39	87.65	0.11	0.18
10	135.97		0.45	
11	82.17	107.62	0.31	0.36
14	11.3	14.68	0.012	0.07
15	147.12		0.497	

None of the subjects were able to ambulate with supervision. All required CGA to min A for safety.

ReWalk has also set a standard for stopping abilities. They suggest that users be able to stop within 2 seconds of a command and within 15 cm from a target. Below is a graph of our patients stopping scores.

Sub.	Distance - 18 (cm)	Time - 18 (s)	Distance-36 (cm)	Time - 36 (s)
2	9.4	2.55		
8	13	1.5		
9	15.55	1.255	30.9	1.7
10	10.5	3.625		
11	22.5	2.69	19.1	1.99
14	Fail	Fail	10.85	2.69 s
15	13.55	1.58		

None of the participants were able to perform advanced level skills without assistance. Three subjects were able to train on advanced skills after 18 sessions and 2 more were able to train after 36 sessions.

The results post 18 sessions:

Sub.	Stairs-Up	Stairs-Down	Curb-Up	Curb-Down	Ramp-Up	Ramp–Down
2	min A	min A	min A	min A	mod A	CGA
10	mod A	mod A	Fail	Fail	Fail	Fail
15	min A	min A	min A	min A	min A	min A

The results post 36 session:

Sub.	Stairs-Up	Stairs-Down	Curb-Up	Curb-Down	Ramp-Up	Ramp-Down
9	min A	min A	max A	mod A	min A	CGA
11	min A	CGA	CGA	min A	mod A	CGA

DISCUSSION

While some subjects were able to meet training thresholds for various skills, none were able to do so with supervision. Additionally, few subjects were proficient enough walkers to move on to advanced skills. However looking at their progressions, none of the subjects had fulfilled their learning potential.

CONCLUSION

Future research should look at increased number of training sessions**.**

CLINICAL APPLICATIONS

This research will help clinicians with plan of care when training patients to take home a ReWalk as well as guide insurance reimbursement.

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EVALUATING AMPUTEE MOBILITY WITH AMPPRO AND PEQ-MS: 4.5 YEAR RETROSPECTIVE CHART REVIEW

Kaluf B.

Ability Prosthetics and Orthotics, Inc.

INTRODUCTION

A retrospective chart review of 4.5 years of outcome measure data from patients with lower limb loss investigated the relationship of patient perceived mobility and functional ability, as well as the effect of age, amputation level and cause of amputation.

The subjective nature of the Medicare Functional Classification Level (MFCL), has frequently cited limitations (Gailey 2006, Kaluf 2014). Recently, Medicare proposed changes to the MFCL guidelines without investigating the potential implications. A more objective understanding or mobility of persons with lower limb loss is needed.

The Prosthetic Evaluation Questionnaire Mobility Subscale (PEQ-MS) rates difficulty performing 12 ambulatory tasks (Franchignoni 2007). The Amputee Mobility Predictor (AMPPRO) assesses mobility and function of lower limb amputees (Gailey 2002). These clinical tools produce quantitative data on mobility and functional outcome.

METHOD

Subjects: 109 lower limb amputees at 11 clinics.

Apparatus: Retrospective chart review

Procedures: Charts reviewed from Electronic Medical Record for AMPPRO, PEQ-MS and demographic data .

Data Analysis: Relevant graphs were plotted to depict relationships between AMPPRO and PEQ-MS scores for patients separated by various characteristics (e.g. amputation level, cause and age)

RESULTS

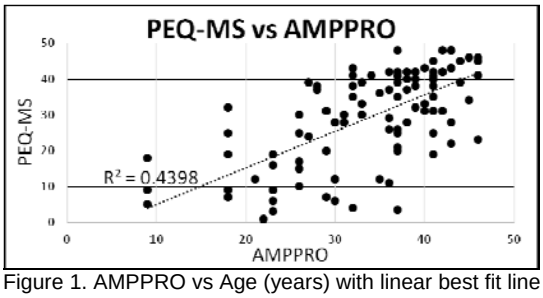

Figure 1. AMPPRO vs Age (years) with linear best fit line and R squared value.

DISCUSSION

There was a positive correlation between PEQ-MS and AMPPRO scores. Average AMPPRO decreased with age. PEQ-MS scores did not follow the same trend. Little difference was seen across amputation level, but traumatic/tumor amputation cause had higher AMPPRO and PEQ-MS scores than dysvascualr/infection.

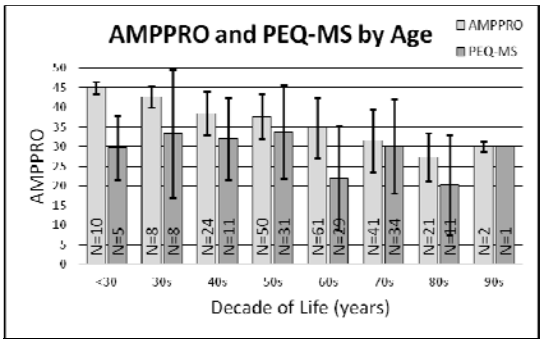

Figure 2. AMPPRO and PEQ-MS average scores per decade of life (years) with standard deviation.

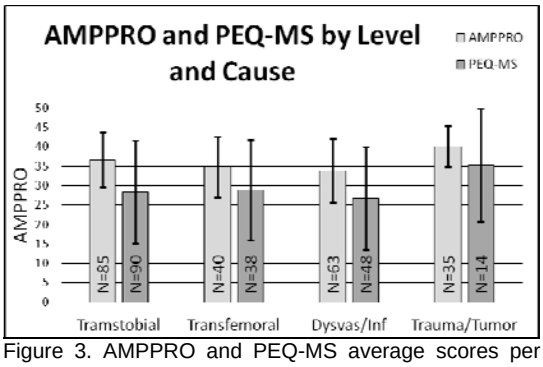

Figure 3. AMPPRO and PEQ-MS average scores per amputation level and cause with standard deviation.

CONCLUSION

Patients with higher functional mobility (AMPPRO) had higher perceived mobility (PEQ-MS). Age and amputation cause had an effect on mobility.

CLINICAL APPLICATIONS

A combination of demographic information such as amputation cause and age and outcome measures such as AMPPRO and PEQ-MS may be more reliable and valid ways to assess and categorize mobility.

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Dilatancy System for Prosthetic Socket Fabrication

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INTRODUCTION

There are 6-billion people live in developing countries, where many disabled persons lack access to prosthetic-orthotic (P&O) services, trained prosthetic personnel, affordable technology and materials. Since 1998, with funding from the National Institute on Disability and Rehabilitation Research (NIDRR), the Center for International Rehabilitation (CIR) and the NUPOC have collaboratively developed innovative dilatancy technologies for the fabrication of prosthetic sockets and orthoses for the world. In order to develop better, cheaper, faster and greener appropriate P&O technologies for low-income countries, we aimed to use low-cost equipment and to eliminate the use of Plaster-of-Paris for fabricating prosthetic sockets or orthoses.

Like vacuum-packaged coffee beans, granules that are enclosed in a flexible container can form and retain any shape as long as the air inside is evacuated. This phenomenon, called dilatancy, was first investigated and patented 66 years ago (Mead, 1949), applied in wheelchair seating system (Germans, 1975) and recently developed into clinical procedures (Wu, 2003, Wu, 2009, Wu, 2010). By placing a bag (or bags) of polystyrene beads or silica sand around a body segment, upon application of vacuum, the granule-filled bag can instantly become a solid negative mold of the body segment. The negative mold can be filled with sand, sealed, and the air inside evacuated to create a positive sand model for vacuum forming prosthetic sockets or orthoses.

METHOD

The development of dilatancy prosthetic socket technologies started with laboratory testing of prototype casting systems on plaster models, followed by clinical evaluation under IRB approved protocol on consented subjects with amputations and finally underwent independent evaluation in the field.

RESULTS

We have successfully developed two plaster-less dilatancy systems for fabricating lower limb prosthetic sockets. The procedure for transtibial prosthetic sockets has been independently evaluated by the International Society for Prosthetics and Orthotics (ISPO) in Vietnam (Jensen, 2005), which confirmed improvement of socket fitting and speedy service provision. The dilatancy casting system has been widely translated in many low-income countries. From 2008 to 2014, 9,627 prostheses were fabricated in Thailand using dilatancy technology. In addition, **nine** prostheses have been fabricated for two landmine-injured elephants using the same approach.

Dilatancy transfemoral system using Spandex casting bag filled with polystyrene beads has been developed pending further clinical evaluation.

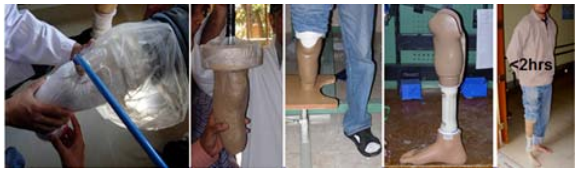

Figure 1, the prosthesis can be made in two hours during a clinic visit. (Photos from Mobility India, India)

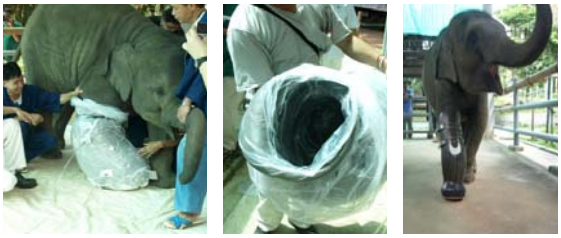

Figure 2, In addition to thousands of lower-limb prostheses for amputees, prostheses were made using dilatancy system for two landmine-injured elephants in Thailand (Photos from Prostheses Foundation, Thailand)

DISCUSSION

Dilatancy casting system is a Spandex casting bag filled with micro-polystyrene beads and sealed in a plastic bag. Under vacuum suction, it shrinks slightly thus works as a pressure-casting for an intimate impression of the residual limb. Being plaster-less, it eliminates waste. The casting system costs minimal to set up and to maintain. It is easy to learn and apply.

CONCLUSION

Dilatancy technology for prosthetics socket fabrication is emerging as a potentially better, cheaper, faster and greener approach that is appropriate for providing service for individuals with amputation worldwide.

CLINICAL APPLICATIONS

Dilatancy P&O technology is an effective alternate to plaster or CAD-CAM-based approaches for prosthetic socket fabrication.

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EFFECTS OF A MODIFIED RUNNING FOOT PROSTHESIS ON USERS' ENDURANCE AND PERCEIVED EXERTION

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INTRODUCTION

For people with transtibial amputations (TTA), use of a prosthesis can facilitate return to a basic level of functional mobility. However, absence of an anatomical foot and ankle still greatly impairs physical performance, resulting in decreased walking speeds, diminished endurance, and restricted ability to participate in life situations. Contemporary energy storing feet (ESF), which use advanced materials and geometric designs, have been developed to address these deficits. Yet even the most advanced ESF do not significantly mitigate the increased energy demands required for walking compared to conventional, rigid prosthetic feet (Hsu, 2006). Running-specific feet (RSF), however, enable runners with TTA to achieve endurance similar to people without limb loss (Brown, 2009) by extending the length and increasing the stiffness of the keel. One limitation to RSF is that the keel-only design does not provide users the stability needed for walking.

A novel modified running-specific foot (mRSF, Figure 1), which combines features of both ESF and RSF, has been developed for use in walking, running, and other daily activities. The mRSF includes an extended carbon keel that is directly connected to the socket, heel springs to facilitate heel-toe walking, and a shell to enable the foot to fit in a typical shoe. Although users' opinions of the mRSF have been positive, evidence is needed to support clinical prescription. The goal of this pilot study was to assess endurance and perceived exertion of people with TTA walking with the developed mRSF and an ESF.

Figure 1 - mRSF

METHOD

Subjects: People with TTA (n=7, mean age=43 yrs) who own comfortable ESF and mRSF prostheses.

Apparatus: Six-Minute Walk Test (6MWT) and Borg Rating of Perceived Exertion (RPE) CR100 scale.

Procedures: Subjects attended a one-time, cross-sectional data collection session where they performed the 6MWT in both prosthetic conditions. Immediately following the 6MWT, they were asked to rate their perceived exertion with the Borg RPE. The order of conditions was randomized to reduce order effects.

Data Analysis: Participants' individual and sample mean 6MWT times and RPEs were plotted for visual inspection and comparison. Group-level statistical testing was not performed, due to the small sample.

RESULTS

6MWT: 5 of 7 subjects increased their distance (in feet) when using the mRSF compared to the ESF (mean difference +65, range: -18 to +230). Two subjects increased their distance by more than 131ft.

Borg: 6 of 7 subjects reported reduced exertion when using the mRSF compared to the ESF (mean difference -13, range: -38 to 0).

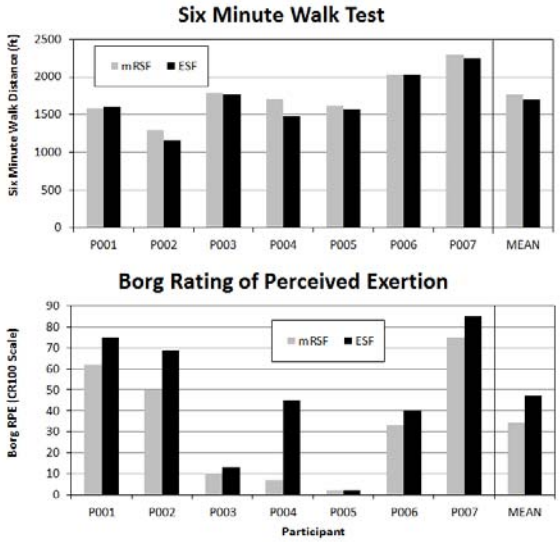

Figure 2 and 3. Individual and mean results for the 6MWT and RPE for the mRSF and the ESF prosthetic conditions.

DISCUSSION

Results of this study suggest that the mRSF may improve endurance while simultaneously decreasing perceived exertion for people with TTA. However, differences were substantial for only 2 of 7 participants for the 6MWT and 4 of 7 subjects for the Borg, indicating that improvements may not be clinically significant for all users.

CONCLUSION

Initial results suggest that the mRSF may facilitate improvements in mobility by increasing endurance while mitigating exertion when compared to traditional ESF in people with TTA. Prospective research is needed to assess mobility and other health outcomes.

CLINICAL APPLICATIONS

The mRSF is a novel prosthetic foot design that may enhance mobility outcomes in people with TTA.

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FOOTWEAR EFFECTS ON PROSTHETIC FEET MECHANICAL PROPERTIES WITH IMPLICATIONS FOR GAIT BIOMECHANICS AND CLINICAL RECOMMENDATIONS

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INTRODUCTION

Studies suggest that the stance-phase mechanical properties of passive prosthetic feet can have considerable effects on mobility outcomes of lower-limb prosthesis users (Major 2014). However, a prosthetic foot is almost always used with a shoe and there remains a lack of understanding of how shoe choices influence the end-user device that has been clinically-optimized based on a patient's mobility level. Some evidence indicates that footwear nullifies the individual and intended design characteristics of prosthetic feet (Curtze 2009), and so this uncontrolled variable may also result in inconclusive findings of comparative effectiveness studies. This study aimed to evaluate the effects of footwear on the mechanical properties of commonly prescribed prosthetic feet to better understand the implications of footwear on clinical recommendations and gait biomechanics.

METHOD

Samples: Five prostheses recommended for an 80 kg patient (left-side, 27 cm) were tested: Cadence (Trulife, Ireland); Seattle Lightfoot 2 (Trulife); Multiflex foot/ankle (Endolite, Miamisburg, OH); SACH (Willow Wood, Mt. Sterling, OH); and Single-Axis (Otto Bock, Germany). The feet were tested barefoot and under four footwear conditions: trainer (Asics, Japan); hiking boot (Timberland, Greensboro, NC); leather dress (Stafford, Dallas, TX); and flat (Mossimo, NY, NY).

Apparatus: Mechanical tests were conducted using a hydraulic-driven materials test machine (Instron, Norwood, MA) to measure force and displacement.

Procedures: The prostheses were loaded to 1230 N at 200 N/s and unloaded using four loading scenarios: heel (15° sagittal declined surface); midstance (level surface); keel (20° sagittal inclined surface); and inversion (15° coronal inclined surface).

Data Analysis: The loading-unloading hysteresis loop was used to estimate energy return (%Joules), and stiffness (N/mm) was estimated as the average slope of a linear approximation of the loading and unloading curves. These estimations were averaged over four loading cycles for each foot-shoe combination.

RESULTS

For initial contact, hysteresis curves for the barefoot condition and estimated energy return for each foot-shoe combination are presented in Figure 1.

DISCUSSION

The hysteresis curves display how articulated devices rapidly transitioned to foot-flat when loaded, but this behavior was normalized with the addition of shoes to mimic function of non-articulated feet. Shoes seem to impair the desired clinical function of articulated devices to quickly achieve a stable base-of-support for patients of low mobility. Apart from the keel where little effect was observed, shoes normalized and decreased stiffness and energy return across feet. Decreased stiffness would simulate greater range-of-motion, but the greatest reduction was observed at the heel and this may exacerbate user perception of 'sinking' into their step. Decreased heel energy return would be beneficial to dissipate loads and protect the residuum, but the reduction in midstance energy return may increase difficulty in energy recovery to aid in transferring weight across the prosthesis and encourage gait compensations. Shoes did not greatly alter keel properties and so prostheses designed to assist late stance push-off may retain this function.

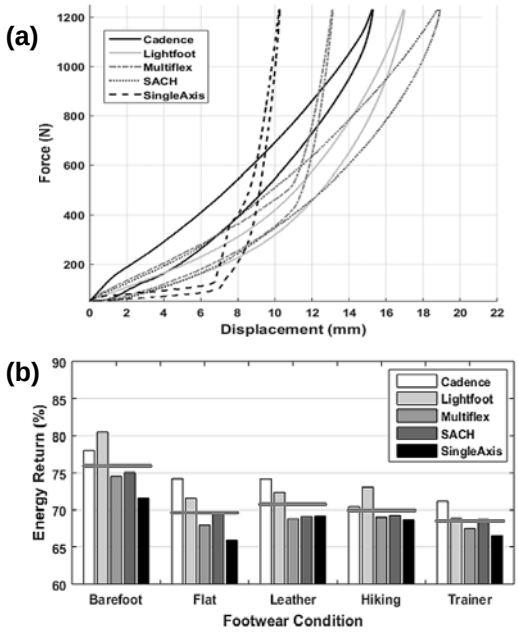

Figure 1. (a) Barefoot hysteresis curves and (b) energy return values for the heel loading scenario.

CONCLUSION

Shoes appear to mute the individual design characteristics of some prosthetic feet, thereby forcing a convergence of mechanical behavior.

CLINICAL APPLICATIONS

Clinicians should be aware that shoes may cause an unpredictable change in mechanical function of the prosthetic setup and alter rehabilitation outcomes. Shoes should be controlled in experimental settings.

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Tuning a powered ankle-foot prosthesis for sloped walking

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INTRODUCTION

When people with a leg amputation walk on level ground using a powered ankle-foot prosthesis, their metabolic demands are equivalent to those of non-amputees over a wide range of speeds (Herr and Grabowski, 2012). However, the metabolic demands incurred when using this powered prosthesis to walk up and down slopes are not known. Further, it is not clear if a powered prosthesis tuned for level-ground walking can accommodate sloped walking.

Thus, we measured and compared the biomechanics and metabolic demands of using a powered prosthesis (BiOM Inc.) to walk uphill and downhill with two tuning strategies; the optimal level-ground tuning (LVL) and adjusted tuning for each slope (ADJ). We hypothesized that the ADJ would result in a lower metabolic demand compared to LVL at all slopes.

METHOD

Subjects: We recruited three males with a unilateral transtibial amputation and fit each with the BiOM.

Apparatus & Procedures: Subjects walked 1.25 m/s on a dual-belt, force-treadmill at 7 slopes (0°, ±3°, ±6°, and ±9°). We measured lower body kinematics and optimized the BiOM tuning for level ground and at each slope by iteratively changing tuning parameters until prosthetic ankle joint biomechanics matched those of non-amputees (NA) within 1 SD (Auyang and Grabowski, 2013). On two consecutive days, we measured metabolic rates via indirect calorimetry for five minutes during standing and walking at each slope for LVL and ADJ with a randomized trial order.

Data Analyses: We calculated ankle joint moment, power, and work using inverse dynamics (Visual 3D; Matlab). We calculated net metabolic cost of transport (COT) using a standard equation and subtracting standing from walking COT. We used one-tailed t-tests to compare tuning strategies and set significance at $p<0.05$.

RESULTS

Prosthetic ankle net work for ADJ were within one standard deviation of non-amputee values (Auyang and Grabowski 2013) at ±3° and +6° and were 21-647% different than LVL values (Table 1).

There were no statistical differences in COT between tuning strategies at any of the slopes (Fig. 1).

DISCUSSION

We tuned the BiOM to match the net ankle work of non-amputees and were able to come within 1 SD at ±3° and +6°. Though there were large differences in biomechanics there were no differences in COT between ADJ and LVL, which refutes our hypothesis. It is possible that the design of the BiOM limits the ability to match biological ankle biomechanics and metabolic costs when walking ±9°. We intend to conduct future studies to further understand the effects of walking up and down slopes with powered prostheses on people with a leg amputation.

Table 1: Differences in ankle biomechanics between ADJ and LVL [(ADJ-LVL)/LVL*100%]. Range of motion (ROM).

Slope	ROM	Peak Moment	Peak Power	Net Work
-9	8.5%	7.3%	-9.2%	-381.4%
-6	-1.5%	0.2%	22.3%	-109.4%
-3	1.4%	5.6%	29.2%	646.9%
3	13.0%	4.7%	62.6%	-21.0%
6	9.7%	4.7%	11.9%	98.7%
9	-7.0%	8.2%	29.9%	235.9%

CONCLUSION

Tuning the BiOM for different slopes resulted in dramatically different biomechanics compared to tuning for level ground, yet there were no differences in metabolic COT between tuning strategies.

CLINICAL APPLICATIONS

Our results provide important information for the prescription of powered leg prostheses. The tuning and control of a powered prosthesis is necessary for normalizing the biomechanics of people with a unilateral transtibial amputation.

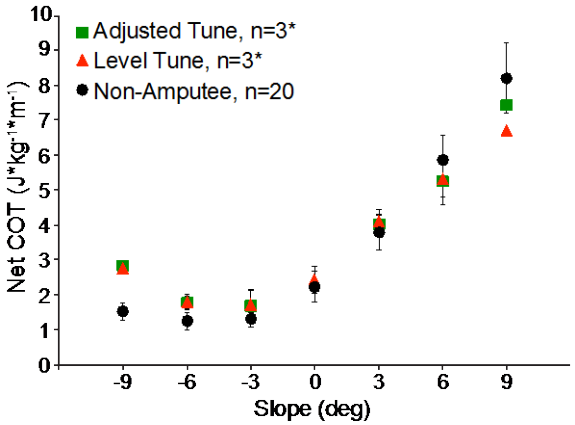

Fig 1: Net cost of transport (COT) for subjects walking at 1.25 m/s. Non-amputee data from (Auyang and Grabowski, 2013). *At +6° n=2, at +9° n=1.

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Evaluation of a viscoelastic ankle-foot prosthesis at slow and normal walking speeds on an able-bodied subject

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INTRODUCTION

Viscoelastic prosthetic feet have been recently introduced that combine adjustable hydraulic dampers with a conventional carbon foot. Ankle function, specifically the moment-angle relation, changes at different speeds. Hence, the properties of a prosthetic foot need to be adapted to the walking speed in order to mimic the behavior of ankle for more normal walking. Ankle function can be reproduced by passive mechanical mechanisms in slow and normal walking speeds without any need for power generating systems (Hansen et. al 2004, Safaeepour et al. 2014,).

Therefore, the aim of the current study was to further improve a viscoelastic ankle foot prosthesis prototype for different walking speeds. An adjustable storage-damping mechanism was embedded in the design to control the ankle hysteresis at slow and normal walking speeds. It was hypothesized that if the damping characteristics of the prosthesis are controlled based on the walking speed, more human-like ankle biomechanics would be revealed. Moreover, the experimental evaluation of the prosthesis on a healthy young male is described.

METHOD

A viscoelastic prosthetic ankle-foot was developed that incorporated two pneumatic assemblies which are engaged in a specific portion of the gait cycle. The units provide adaptable stiffness properties during a gait cycle (Safaeepour et al 2014). To improve the design, a damping control mechanism was added to the PF unit which was applied at the instant of heel strike and heel off. According to the walking speed, damping could be manually regulated in late stance by adjusting the opening size of the damping valve (Figure 1). The manufactured prototype was preliminarily tested on a healthy volunteer using an adaptor. The subject was a male, 26 years of age, 70 kg body mass, and 180 cm height. The participant provided written informed consent. Gait analysis was performed with five Vicon cameras and two Kistler force plates. The participant was asked to walk at self-selected slow and normal walking speeds while wearing the prosthesis while the damping valve was manually adjusted based on walking speed.

RESULTS

The general shape of the moment-angle loop at slow walking speed was in agreement with the normal ankle in which the curve showed a looped hysteresis curve. Figure 2 represents the prosthetic joint angle, at six walking trials with slow (dashed lines) and normal speeds.

Figure 1. Manufactured Prototype

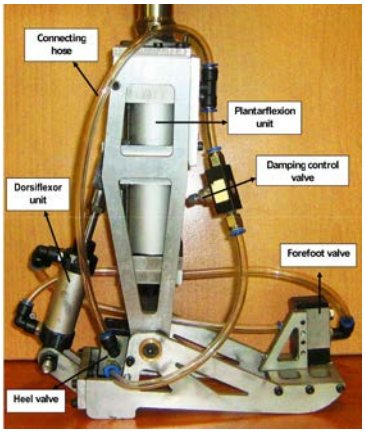
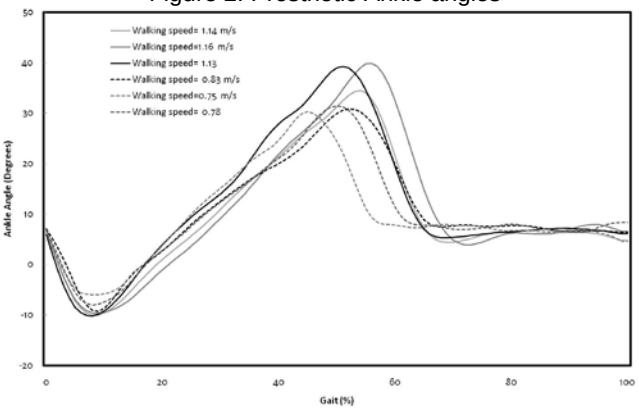


Figure 2. Prosthetic Ankle angles



DISCUSSION

Findings of this study suggest that the viscoelastic ankle foot prosthesis prototype could mimic the natural ankle biomechanics in slow and normal walking speeds.

CONCLUSION

The mechanical mechanism is an advantage of this approach which excludes the need for electronic control while providing a smooth normal-like pattern for joint motion.

CLINICAL APPLICATIONS

Understanding the potential benefits of a controllable damping mechanism based on the gait speed can inform the design of new prosthetic feet.

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Stakeholder Input on a Residual Limb Monitoring System

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INTRODUCTION

The interface between a prosthetic socket and residual limb is often problematic with socket fit and suspension issues leading to skin problems and reduced daily prosthesis use, mobility and quality of life (Meulenbelt et al. 2006). Sensing inside the socket is proposed as a way for prosthetists to both monitor and troubleshoot these socket fit and suspension problems (Hafner & Sanders, 2014). However, existing sensors have limited clinical utility because they are bulky, wired, and sometimes require mounting on the socket or liner in a manner that is uncomfortable and/or destructive (Mak et al. 2010). Recent development of thin, flexible, 'skin-like' sensors (Kim et al. 2011) may address some of these problems, leading to the development of a residual limb monitoring system. To ensure clinical utility of any such system, input from stakeholders is necessary. Hence, the purpose of this study was to gather information from prosthetists and prosthesis users about the residual limb problems they encounter, how a residual limb monitoring system might be used in clinical practice, and how it might best be configured.

METHOD

Two focus groups were held, one with certified prosthetists (CP) and the other with lower-limb prosthesis users (Px Users). An experienced moderator guided focus group discussions using scripts comprising of 8-9 open-ended questions. The questions solicited information about residual limb problems and management; how users and clinicians might want to measure conditions within the sockets; and how a sensor/monitoring system might look to the end users. Discussions were audio recorded and transcribed. A team of four investigators participated in thematic data analysis (Guest et al. 2012) to assess prosthetists' and prosthesis users' perceptions, feelings, knowledge, and behavior of residual limb problems and potential methods for monitoring socket issues and residual limb health.

RESULTS

Participants in the CP group (n=7; 3 females, 4 males) came from a mix of practice settings and had 4 to 33 years of clinical experience. Participants in the Px Users group (n=7; 5 females, 2 males) were diverse in their level of amputation (TTA and TFA) and etiology (trauma, vascular, infection, congenital), and had <1 to 40 years of experience using lower-limb prostheses.

Our preliminary analysis suggests that skin breakdown, sweating and volume fluctuation were the major residual limb problems for participants (Fig. 1); suggested useful measures included pressure and temperature; and using a wireless app on a portable electronic device was favored.

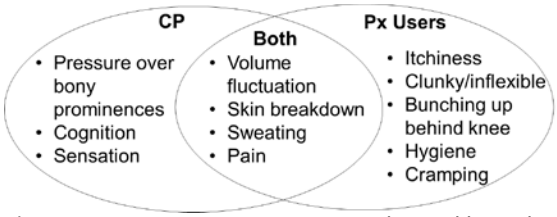

Figure 1. Focus group responses to *"What problems do lower-limb prosthesis users experience with their residual limb(s)?"*

DISCUSSION

The residual limb problems reported by focus group participants were similar to findings from the literature regarding problems that interfered with prosthesis use (Meulenbelt et al. 2006; Klute et al. 2009). Both prosthetists and prosthesis users indicated in-socket temperature was a measurement priority and the immediate perceived benefit was in troubleshooting socket fit issues. They were generally in favor of a wireless sensor system to monitor residual limb health in the clinic and perhaps short term at home so long as the system was easy to use and inexpensive.

CONCLUSION

In order to develop a user-friendly residual limb monitoring system for use in the clinic and home environment, the input of end-users is critical. It seems clear that for widespread clinical use, system benefits would need to strongly outweigh any inconveniences to either the prosthetist or prosthesis user.

CLINICAL APPLICATIONS

Focus group input will be used in the development of a residual limb monitoring system using wireless 'skin-like' sensors (Kim et al. 2011) that can measure temperature and pressure inside a prosthetic socket, helping to detect residual limb issues before they become problematic.

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PSYCHOMETRIC PROPERTIES OF SELF-REPORT OUTCOME MEASURES FOR PROSTHETIC APPLICATIONS

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INTRODUCTION

Self-report outcome measures are well suited to measurement of prosthetic outcomes and are advocated for use in clinical practice and research. However, specific information about each measure's psychometric performance is needed to help clinicians and researchers select appropriate instruments and interpret the information they provide.

Test-retest reliability, for example, is a key factor in distinguishing measures recommended for individual-level applications (e.g., monitoring a patient's change over time) from group-level applications (e.g., comparing groups in a clinical trial). It is generally accepted that measures should demonstrate reliability of 0.7 or greater for comparisons between groups of people (Reeve, 2013) and 0.9 or greater for applications that involve decisions about individuals (Fitzpatrick, 1998). *Mode of administration (MOA) equivalence* is needed to demonstrate that scores obtained from different methods of administration (e.g., paper or electronic) are directly comparable (Coons, 2009). Evidence of equivalence would allow administrators to choose the format most appropriate for the respondent. *Standard error of measurement (SEM)* and *minimal detectable change (MDC)* are properties that help users interpret scores and score changes. SEM and MDC describe expected variations in a score and minimum differences that can be considered "true" change, respectively.

Although psychometric properties such as these can improve instruments' usability and interpretability, they have not been established for many measures used in prosthetics. Therefore, the purpose of this study was to assess reliability, MOA equivalence, SEM, and MDC of five self-report measures that have been advocated for use in prosthetics.

METHOD

Subjects: Participants (n=201) with unilateral lower limb loss, mean age of 60 years, most reported either traumatic (60%) or dysvascular (23%) etiologies.

Apparatus: A standardized, self-report survey included the Prosthetic Limb Users Survey of Mobility 12-item short form (PLUS-M), the Prosthesis Evaluation Questionnaire Mobility Subscale (PEQ-MS), the Activities Specific Balance Confidence Scale (ABC), the Socket Comfort Score (SCS), and the Quality of Life in Neurological Conditions Applied Cognition/General Concerns (NQ-ACGC).

Procedures: Test and retest surveys were administered to all participants via paper and/or electronic methods over a 48-72 hour period. Participants were randomly assigned to one of three study arms (i.e., electronic-only, paper-only, or mixed) based on modes of administration.

Data Analysis: Reliability of each instrument was quantified using the intraclass correlation coefficient (ICC 3,1). ICCs were compared across study arms to evaluate MOA equivalence. Reliability ICCs were used to calculate SEM and MDC(90).

RESULTS

Retest surveys were taken, on average, 2 (SD=0.2) days after the test survey. Time to complete the test and retest surveys was 12 (SD=7) and 10 (SD=6) minutes, respectively. Reliability ICCs, determination of MOA equivalence, and estimates of SEM and MDC were determined from participant scores (Table 1).

Table 1- Psychometric properties of outcome measures.

MEASURE	ICC	MOA =	SEM	MDC
PLUS-M (T-score)	0.96	yes	1.93	4.50
PEQ-MS (0-4)	0.92	yes	0.24	0.55
ABC (0-4)	0.95	yes	0.21	0.49
SCS (0-10)	0.74	no	1.18	2.73
NQ-ACGC (T-score)	0.88	yes	2.87	6.67

DISCUSSION

Tested measures all have moderate-to-high (>0.7) test-retest reliability, indicating that they are suitable for group-level comparisons, like quality improvement programs. Select measures (PLUS-M, PEQ-MS, and ABC) have high reliability (>0.9) and are suitable for individual-level applications, like monitoring patients over time. Comparisons of ICCs indicate measurement equivalence across paper and electronic MOAs for all measures, except the SCS. Further research is needed to assess the use of the SCS for individual-level applications. SEM and MDC estimates derived in this study can be used to interpret scores obtained from each instrument.

CONCLUSION

Estimates of test-retest reliability, MOA equivalence, SEM, and MDC derived in this study can be used to inform instrument selection and facilitate interpretation of resultant scores.

CLINICAL APPLICATIONS

Clinicians can use information from self-report outcome measures to monitor patients and assess the effectiveness of prosthetic interventions. Measurement properties, including test-retest reliability, MOA equivalence, SEM, and MDC, can aid them in selecting measures and interpreting scores.

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Direct medical costs of accidental falls for adults with above knee amputations.

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INTRODUCTION

As medical care in the US shifts from a fee-for-service to fee-for-value model it is important to understand the relationship between the cost of the services provided and their outcomes (Porter, 2010).

Active individuals with above knee amputations (AKA) are provided a microprocessor controlled knee (MPK) with the belief that the prosthesis reduces their risk of falling (Hafner et al, 2007; Kahle et al, 2008). Yet, the improved quality of life is not without a price; a MPK costs Medicare $21,957 more than a swing and stance control knee (Noridian Healthcare Solutions, 2015).

A cost-benefit analysis has not been performed because the direct medical costs of a fall have never been determined. The rate of limb loss is projected to more than double between 2005 and 2050; understanding the relationship between the cost of an MPK and the medical costs it can help avoid is increasing important (Ziegler-Graham et al, 2008). Thus, we undertook an effort to estimate the six-month direct medical cost of falls for adults with an AKA and compare these costs with the incremental cost of a MPK.

METHOD

Subjects: 77 adults with AKA (28 female, 49 male; 48 with a prosthesis; 16 with a prosthesis who experienced a fall) were included in the analysis.

Procedures: Retrospective study of falls resulting in an emergency department visit or hospitalization from 2000 to 2014. Medical records, administrative data, and chart reviews were used.

Data Analysis: Patient demographics, Elixhauser comorbidities, and standardized medical costs adjusted to 2014 dollars were included. A modification of the Bayesian structural time series approach to predict six-month costs following a fall event had the event not occurred – this cost is then compared to observed costs (Brodersen et al, 2015) was used.

RESULTS

The mean six-month direct medical cost of falls for adults with above knee amputations was $25,652 ($10,468 - $38,872) for those who were hospitalized (Figure 1). The mean cost for those only admitted to the emergency department was $18,091 ($-7,820 - $57,368).

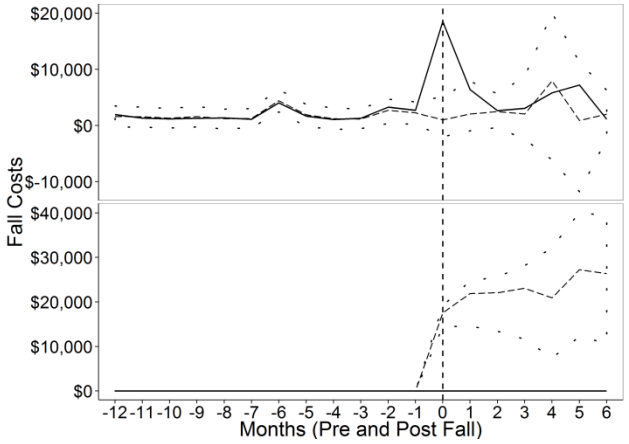

Figure 1. Average hospitalization fall costs. The solid line is observed costs, dashed line is predicted costs, and dotted lines bound the 95% credible intervals. A vertical dashed line indicates the fall month. The top panel depicts the monthly costs and the bottom panel is the cumulative monthly costs

DISCUSSION

This is the first estimate of the cost of falls for individuals with an AKA. The cost is similar to the costs estimated for elderly individuals who fall and are hospitalized ($25,652 and $27,745 respectively) (Bohl et al, 2010). Providing an MPK has the potential to avoid costly falls and reduce overall direct medical costs.

CONCLUSION

Falls that require medical intervention are equal to or slightly more than the incremental cost of providing a MPK to an individual with an AKA.

CLINICAL APPLICATIONS

Comparison of the cost of falls and cost of a MPK offers providers additional evidence to support the decision to prescribe a MPK.

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Concurrent Validity of Lower Limb Domains of the Continuous Scale Physical Functional Performance-10 (CS-PFP10) Assessment in Transfemoral Amputees

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INTRODUCTION

Validated outcome measures for persons with lower limb amputation are limited. Measures that can cross diagnostic groups are even more rare due to poor sensitivity and other psychometric properties in specific diagnostic groups. With ≈ 350,000 Americans with transfemoral amputation (TFA) and nearly 2M in the US presently, the limited ability to measure function in a valid manner is problematic. The continuous scale physical functional performance test (CS-PFP-10) has shown promise in persons with TFA. This is a test, validated in other diagnostic groups including frail elderly, wheelchair users, strok victims, cardiac compromise and others. The test assesses physical function in 5 domains as well as total function and independence. This study sought to determine the concurrent validity of the portions of the CS-PFP-10 that did not involve the upper extremities in comparison to measures of comparable function that have established face validity in this population.

METHOD

The study was approved by the USF IRB. An observational design was used. Unilateral TFAs (≥K3), who used microprocessor knees for ≥1y were recruited. Subjects were 18-85y and free of medical comorbidities. TFAs' preferred prostheses were evaluated for proper fit, alignment and function and to assure no problems within the last 90 days in order to participate.

CS-PFP10 was administered via standardized procedure (i.e. certified test site, script dialogue, trained rater; all reported elsewhere). CS-PFP10 scores 10 ADLs in time, distance, and mass. Raw data reflects physiologic functional domains. Testing requires ≈30min. Raw data (time, distance, mass) are converted to summary scores with a validated algorithm in licensed software. Scaled from 0-100, summary scores include CS-PFP total score (CS-PFP TOT) and 5 physiologic domain scores: upper body strength (UBS) & flexibility (UBF), balance & coordination (BAL), lower body strength (LBS) & endurance (END).

Data were entered into a database and examined for normality. Pearson product moment correlation values (r square) were calculated for each test pair (i.e. respective PFP total or domain score with a measure of concurrent validity). We considered correlations of 0 to ±0.49 as weak, ±0.50 to 0.79 as moderate, and ±0.80 to 1.00 as strong. Statistical significance was also assessed with a critical alpha of 0.05 to determine statistical significance for test pairs.

RESULTS

10 TFAs (age: 41.3y±15.5; BMI: 25.2±4.3kg/m^2) completed the study. Six lost their leg to trauma, 3 to malignancy and one to vascular disease.

All 5 selected measures which included the AMP, a 75m self-selected walking speed test, an instrumented balance test (the Biodex SD Limits of Stability Test [LOS]) and a timed stair descent test moderately correlated with their respective matched PFP score. For example, Lower Body Strength (LBS) moderately correlated (r square=0.63) with stair descent time as a surrogate measure of strength. Further, all of the matched test values were statistically significant at $p \leq 0.01$.

Table: Concurrent Validity Test Pairs.

PFP Domain	Comparative Test	r square
Total PFP	AMP	0.64
Total PFP	75m SSWS	0.73
PFP BAL	Biodex SD LOS	0.58
PFP END	75m SSWS	0.66
PFP LBS	DN Stair Time	0.63

All correlations statistically significant ($p \leq 0.01$) between tests.

DISCUSSION & CONCLUSION

It was surprising that the 75m SSWS test correlated more strongly than the AMP did with total physical functional performance however both were moderately correlated. The 75m SSWS test had a comparable relationship with the Endurance domain of function. Downstair walking and the instrumented posturography tests were both reasonable surrogate measures for lower body strength and balance respectively. These preliminary results are promising and suggest that further psychometric testing is warranted in this population. The results also suggest that preliminary uses of the CS-PFP-10 test in persons with TFA that detected differences were likely valid comparisons. The greatest concern with these results centers upon the small sample which was predominantly of traumatic etiology in a sample of middle aged community ambulators. Further study is indicated prior to generalizing results to other subsets of persons with TFA.

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Smart Activity Monitors and Use by Lower Limb Amputees

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INTRODUCTION

It is a widely accepted premise: health is so highly correlated with physical activity that clinicians are constantly encouraging more physical activity from their patients (Siegel, 1995). Lower limb amputees, who often present with numerous comorbidities, are no exception, particularly when one considers their activity levels are far below their non-amputee cohorts (Tudor-Locke, 2009; Klute, 2006). While many believe the expensive technology in next generation limbs (Goldfarb, 2013) will result in greater activity levels that may address amputee health disparities, what if there is another, less expensive way?

One approach to encouraging greater activity involves simply wearing an activity monitor; doing so has increased activity, promoted weight loss, and decreased blood pressure in other patient populations (Bravata, 2007; Richardson, 2008).

The aim of this research is to determine if evidence supporting the use of inexpensive, smart activity monitors to increase activity levels extends to the lower limb amputee population and to determine if lower limb amputees are willing to use smart activity monitors as part of their daily life.

METHOD

Subjects: 21 lower limb amputees provided informed consent to participate in this IRB-approved protocol (16 transtibial, 5 transfemoral; 13±13 years post-amputation; n=10 trauma, n=1 diabetes, n=4 secondary to infection, n=6 other causes).

Smart activity monitor: Fitbit Zip (Fitbit Inc., San Francisco, CA).

Procedures: Participants received a smart activity monitor (and replacements or new batteries when needed) and taught how to use and sync it. Subjects were blinded to feedback for the first two weeks to establish a baseline activity level. Afterwards, subjects could get activity level feedback from the smart activity monitor display and access their historical data on the Fitbit website. Participants also received virtual achievement awards with a target activity level set at 10,000 steps/day. Other important milestones, such as the greatest number of steps taken in a day and incremental lifetime distance achievements (e.g., 100 miles, 250 miles, etc.), were awarded.

Data Analysis: Participant data was downloaded from the Fitbit website to calculate baseline and post-baseline activity levels (steps/day), and use patterns. A habitual user was defined as someone who wore the smart activity monitor for at least 75% of the days enrolled in the study.

RESULTS

The median duration of participation was 5 months (range: 2 to 20 months) in this on-going study. The baseline (no feedback) and post-baseline activity levels (steps/day) are shown in Table 1. After the baseline period, transtibial amputees increased their activity 1%, transfemorals increased their activity 14%, while the entire sample population taken together increased their activity 4%. Fifteen of the 21 participants met the criteria for habitual use.

	BASELINE	POST-BASELINE
Transtibials	5331±2123	5380±1754
Transfemorals	5617±2423	6392±1507
All	5399±2138	5621±1720

Table 1. Activity levels (steps/day; mean ± standard deviation) of amputee participants.

DISCUSSION

Blinded studies (no feedback to the wearer) have shown that lower limb amputees take less than 6,000 steps/day (Klute, 2006; Stepian, 2007), a result comparable to the baseline data of this study. As observed in other populations (Bravata, 2007; Richardson, 2008), providing feedback resulted in additional activity among lower limb amputees.

CONCLUSION

Lower limb amputees appear to be willing to use smart activity monitors as part of their daily lives, resulting in higher activity levels.

CLINICAL APPLICATIONS

An inexpensive device (~$50) may increase the activity levels, and perhaps health, of lower limb amputees.

ACKNOWLEDGEMENT

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Assessing rehabilitation of a recent unilateral transfemoral amputee: clinical outcome measures and Modus Trex™

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INTRODUCTION

Assessing rehabilitation potential and documenting clinical outcome for persons with lower limb loss has become increasingly important. The Veterans Administration (VA) has begun reimbursing for an activity monitor (Modus Health StewWatch™), and parameters calculated from step activity (Modus Trex™) may provide insight to mobility. These parameters have not been reported in literature and may not be well understood by everyday clinicians.

This case study highlights the clinical outcome measure and step activity data that can be collected during routine prosthetic rehabilitation and can be used to assess rehabilitation potential and document clinical outcomes.

METHOD

Subject: 60 year old female, recent unilateral transfemoral amputation secondary to failed knee surgery, 150 lb, MFCL K-3, lives independently

Apparatus: Amputee Mobility Predictor (AMPPRO), Prosthesis Evaluation Questionnaire – Mobility Subscale (PEQ-MS), Activities Specific Balance Confidence Scale (ABC), Prosthetic Limb Users Survey of Mobility (PLUS-M), Modus Trex™ (Modus Health)

Procedures: Patient was fit with a preparatory transfemoral prosthesis including an ischial containment socket, seal-in gel liner with suction suspension, 4-bar mechanical knee without hydraulic cylinder, hydraulic ankle/foot. A Modus Health StepWatch™ was attached to the prosthesis during her inpatient rehabilitation stay and the months following her discharge to home.

RESULTS

Outcome measure data and Modus Trex™ data were recorded during prosthetic delivery and follow up appointments. The results are depicted in Figures 1 and 2. Additionally, the patient walked an average of 832 steps/day at the initial time point, and 1,733 steps/day at the final time point.

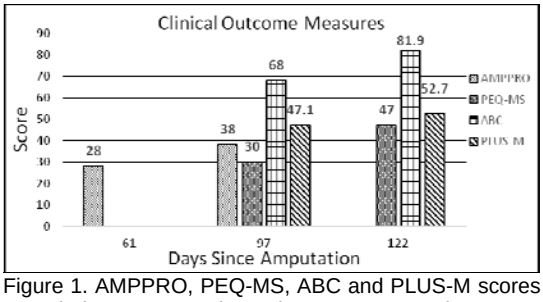

Figure 1. AMPPRO, PEQ-MS, ABC and PLUS-M scores recorded at 61, 97, and 122 days post amputation

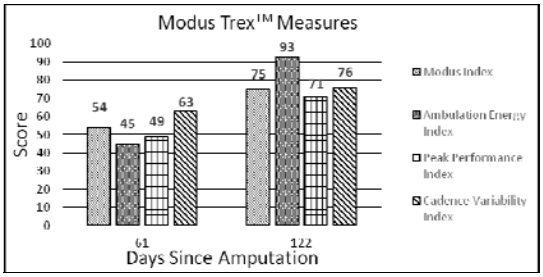

Figure 2. Modus Index, Ambulation Energy Index, Peak Performance Index and Cadence Variability Index from the Modus Trex™ at 61 and 122 days post amputation.

DISCUSSION

The patient improved in all clinical outcome measures through the initial prosthetic rehabilitation. The initial AMPPRO score was outside of the range of published data for MFCL K-3 patients (Gailey 2002), but at the second time point, her score fell within the K-3 range. The patient exhibited an increase in balance (ABC) and perceived mobility in the community (PEQ-MS and PLUS-M) as she gained experience with her prosthesis. She increased step activity (steps/day) and increased all the Modus Trex™ parameters. The Cadence Variability Index showed that the patient was above the 50th percentile, and the Ambulation Energy Index increased faster than any other parameter.

CONCLUSION

The clinical outcome measures and data from Modus Trex™ showed improvement in functional mobility (AMPPRO) perceived balance (ABC) and mobility (PEQ-MS and PLUS-M), as well as performance in the community (StepWatch™). The specific parameters from Modus Trex™ will become more useful for interpreting as more results are published in the literature.

CLINICAL APPLICATIONS

This case study demonstrates how functional outcome measures, patient-reported outcome measures and a sensor instrument can be used to document mobility and rehabilitation in a comprehensive manor

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COMPARISON BETWEEN A NOVEL MAGNETIC LOCKING INTERFACE AND A PIN LOCKING SYSTEM FOR SUSPENSION OF LOWER LIMB PROSTHESES

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INTRODUCTION

Pin locking systems are a common choice for suspension of lower limb prostheses. Benefits of pin systems include their reliability and simplicity. However, pin systems provide less control of the residual limb within the socket compared to other suspension options, including control of vertical pistoning (Klute, 2011) and socket rotation (Ali, 2012).

We developed a new, liner-assisted suspension mechanism called the magnetic locking interface (MLI) (Figure 1). Three pairs of magnets draw the liner into the socket-mounted MLI connector. Once the male connector (attached to the liner) is seated into the distal receiver, the connection is secured with an external latch.

Figure 1. MLI connector.

The purpose of this investigation was to compare the performance of the MLI connector to a commercially available pin system in individuals with lower limb amputations.

METHOD

Subjects: 5 males and 2 females (age 49 ± 18) with unilateral transfemoral amputation (1 K2, 4 K3, 2 K4 functional level) participated.

Apparatus: Two test sockets were fabricated from a single mold of each participant, one with the MLI and one with a pin and shuttle lock installed. Subjects used the same silicone locking liner with both systems. All test prostheses used a Mauch knee and a size-matched foot. Pigment transfer between the liner and socket was used to measure socket rotation relative to the liner during walking.

Procedures: Activities included walking at self-selected speeds over level ground in a laboratory, repeated donning and doffing and completing an *ad hoc* questionnaire.

Data Analysis: Differences between the MLI and pin systems in socket rotation during walking were determined using a paired t-test.

RESULTS

Decreased socket rotation relative to the liner was observed with the MLI (6.3 ± 1.9°) compared to the pin system (16.4 ± 6.7°) (p=0.006).

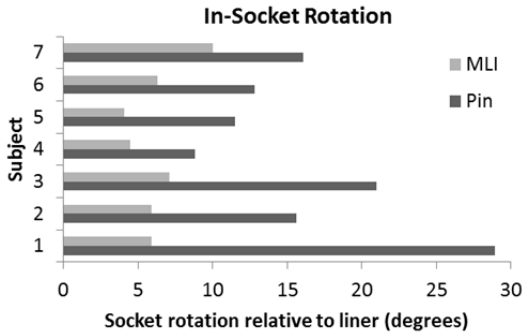

Figure 2. Socket rotation relative to the liner during walking for each subject using the MLI and pin systems.

Five of seven subjects reported that the MLI provided more secure suspension and four of seven reported improved socket comfort using the MLI. Four of seven subjects reported that it was more difficult to determine the correct way to don the prosthesis and that donning took more time with the MLI compared to the pin system.

DISCUSSION

Controlling socket rotation helps maintain prosthetic components in proper alignment, facilitating better gait mechanics. Decreased socket rotation is also a possible explanation for subject reports of more secure suspension and improved comfort using the MLI. Additional practice and design improvements may facilitate easier donning with the MLI.

CONCLUSION

The MLI connector provided greater control of socket rotation during walking than a pin system. Subjects reported improved socket comfort and more secure suspension using the MLI.

CLINICAL APPLICATIONS

Control of socket rotation is a challenge in prosthetic fitting, especially for patients with significant redundant tissue on their residual limbs. The novel MLI connector could provide similar benefits as pin suspension while providing greater control of socket rotation.

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March 9 – 12, 2016

A COMPARISON OF GAIT PARAMETERS BETWEEN ABLE BODIED PROSTHETIC EMULATOR USERS AND PEOPLE WITH TRANS TIBIAL AMPUTATIONS

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INTRODUCTION

Development of advanced prosthetic components requires multiple iterations of testing, design refinement, and retesting. Component testing has traditionally used people with amputation. However, this can be difficult given limited number of potential research subjects available due to the relative rarity of amputation and the confounding factors related to the many comorbidities inherent in this population. Some researchers have accelerated the development process by using individuals with intact limbs wearing prosthesis emulators (Collins, 2010). If these ankle-fixation boots accurately replicate prosthetic gait, they could allow for a larger population of subjects for testing and development of prosthetic foot/ankle systems.

The objective of this study was to provide preliminary validation of ankle-fixation boots as an emulator of prosthetic gait, specifically looking at temporospatial aspects of gait.

METHOD

Subjects: Five males (44.6 ± 12.7 yrs, 92.2± 17.0 kg, 185.5± 16.2 cm) with unilateral trans-tibial amputations (TTA) and five males (86.4 ± 6.8 kg, 178.8 ± 5.36 cm) with intact limbs (EMU) completed this IRB approved study.

Apparatus: Subjects in the intact-limb group utilized an ankle-foot orthosis (Össur, Rebound Air Walker), with a plate attached to allow the addition of a prosthetic foot to the bottom, unilaterally. A boot with a 10 cm lift was worn on the contralateral limb to account additional height provided by the prosthetic foot. An even walkway (7.3 x 0.8m) was used to ambulate on while an eight camera motion captures system (Vicon Motion Systems, Oxford, UK) recorded limb kinematics.

Procedures: A 39-marker set (Vicon PlugInGait) was applied to each subject. The subject walked five times down the walkway to a metronome (108 bpm) with one of three foot conditions (order randomized) An Endolite Multi-flex foot with soft, medium, and firm interchangeable ankle stiffnesses were utilized.

Data Analysis: A mixed ANOVA was used to compare step length, percent time spent in stance, and Froude number across foot stiffnesses and between groups. Statistical significance was declared at $p < 0.05$.)

RESULTS

There were no significant effects of foot stiffness or group, and no interaction effect. Group effect p-values were as follows: rt. step length (p=0.27), lt. step length (p=0.16), rt. stance % (p=0.34), lt. stance % (p=0.62), and Froude number (p=0.98).

	Soft		Medium		Firm		Effect of Stiffness (p value)
	TTA	EMU	TTA	EMU	TTA	EMU	
Rt Step Length (m)	1.19	1.15	1.18	1.14	1.18	1.13	0.71
Lt Step Length (m)	1.20	1.14	1.21	1.14	1.20	1.15	0.37
Rt Stance %	66.6	63.6	66.9	65.4	65.6	65.7	0.60
Lt Stance %	63.9	63.8	63.1	63.8	62.8	64.2	0.70
Froude Number	0.13	0.13	0.13	0.14	0.14	0.13	0.58

Table 1. Mean results for different ankle stiffnesses within each group.

DISCUSSION

There were no significant differences between groups with any temporospatial variable indicating the emulator boots did replicate prosthetic gait. Froude number was used instead of gait speed and cadence as this would be account for the increase in leg length with the prosthetic emulators to show walking dynamics were constant between groups.

CONCLUSION

The emulators were able to replicate the prosthetic gait parameters measured. While these findings suggest that emulators could be valuable tools, further research is needed to test their validity across other biomechanical variables (e.g. joint moments, center of mass work, etc.).

CLINICAL APPLICATIONS

A reasonable and cost-effective method of replicating transtibial amputation gait can help further research, via the use of prosthetic emulator boots. This will create a larger subject pool, thus providing the availability to perform more research that can potentially benefit the amputation population.

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Stair Ascent and Descent with Genium and C-Leg Knees

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INTRODUCTION

Unilateral lower limb pathologies commonly lead to a step-to (ST) gait pattern during stair walking. However, the C-Leg has enabled transfemoral amputees (TFAs) to descend stairs using a step-over-step (SOS) gait pattern. This study presents gait patterns used by TFAs in a randomized cross-over study of the Genium and C-Leg prosthetic knees. Gait patterns were classified for each knee using 3D motion capture data to identify the leading foot and the gait style as ST or SOS.

METHOD

Subjects: 5 Non-amputee controls & 20 TFAs (19 Male, 6 Female). Study protocols were approved by the University of South Florida's IRB, and informed consent was obtained prior to data collection.

Apparatus: Randomized experimental A-B crossover. 8 camera Vicon (Oxford, UK) motion analysis system.

Procedures: Control subjects' gait was recorded for reference prior to recording TFAs. TFAs were randomized to C-Leg or Genium knee for phase A testing. After an accommodation period, subjects were asked to demonstrate a step-over gait (if able) and their normal gait (if different) for stair ascent and descent. Amputee subjects switched knee type, and re-accommodated, prior to returning for phase B testing. While accommodating to the Genium knee, subjects were trained to utilize novel features of the knee (Highsmith et al., 2014).

Data Analysis: Motion analysis data were filtered using a weighted moving average to remove noise. Markers positioned superior to the 2nd metatarsal head (or approximate location on prosthetic side) were used to track footsteps. Knee flexion data were calculated based on marker clusters placed on the thigh and shank of each subject.

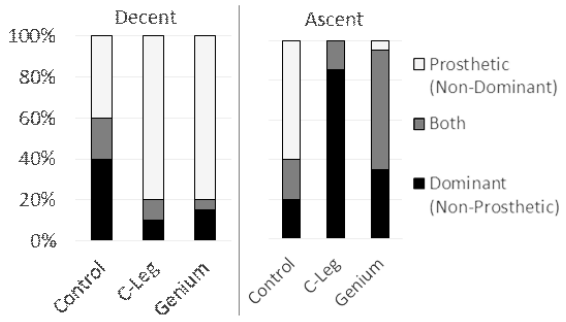

Figure 1. Percent of subjects leading with; only the Prosthetic (Non-Dominant) side (White); both sides (Gray); and only the Dominant (Non-Prosthetic) side (Black) for stair descent & ascent: Controls, C-Leg, Genium.

RESULTS

Subjects demonstrated several gait patterns. Controls had symmetric steps, always used SOS gait, and did not show a strong preference for leading foot in either ascent or descent. TFAs were more variable when deciding the leading foot. TFAs tended to prefer to lead with their prosthetic foot during descent, and the contralateral side for ascent. During ascent while using the Genium knee subjects were more likely to lead with the prosthetic foot.(Figure 1) During descent, most TFAs led with their prosthetic side, placed the heel on the step's edge and rode the knee resistance down, regardless of knee.

On ascent, TFAs either used ST gait, with little change in knee flexion, or SOS gait. Within SOS TFA gait, several variations were observed. Some used SOS without using pronounced knee flexion. This was the primary pattern used 5/20 TFAs able to use SOS with C-Leg. While using Genium, 18/20 TFAs could activate knee flexion and demonstrate an ascent pattern similar to controls. However, many TFAs also exhibited exaggerated knee flexion and heel rise with Genium use during ascent.

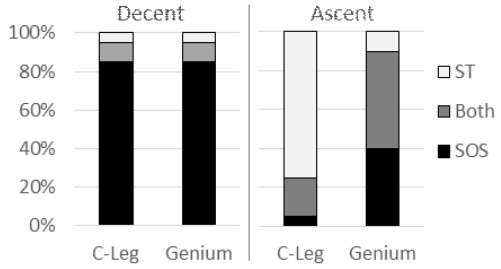

Figure 2. Gait style of TFAs during stair descent & ascent.

DISCUSSION

Genium significantly ($p<0.001$, McNemar's) increased the number of amputees able to ascend stairs using a SOS gait pattern, but did not show significant difference during stair descent. Results agree with previous studies evaluating the C-Leg and X2 knees, that found improvement in gait parameters with use of the X2 knee (Whitehead et al., 2014) for stair ascent.

CONCLUSION

Genium knee use seems to decrease TFA movement impairment during stair ascent.

CLINICAL APPLICATIONS

Genium knee use may be beneficial for users who want or need to ascend stairs regularly.

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AMBULATION-ACTIVITIES DIFFICULTY AND RESIDUAL LIMB PAIN, SOCKET-FIT, AND BALANCE-CONFIDENCE

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INTRODUCTION

Lower limb amputation (LLA) incidence increases after 50 years of age (Dillingham, 2002). Restoration of ambulation ability following an amputation may promote independence and improve social function (Fortington, 2013). Identifying factors that may contribute to ambulation-activity difficulty may ultimately guide interventions. ***Purpose*****:** The primary objective of this analysis was to explore relationships among suspected factors, i.e. residual limb pain, socket-fit comfort, and balance-confidence, and difficulty with self-reported ambulation-activities, among individuals with LLAs. We hypothesized that these factors would be independently associated with ambulation-activity difficulties, with the strongest associations for residual limb pain. Secondary objectives included determining if there were any associations among residual limb pain, socket-fit comfort, and balance-confidence and which ambulation-activities were perceived as most difficult.

METHOD

Subjects: Data was collected from 19 patients with unilateral transfemoral or transtibial amputations who were currently using a prosthetic device.

Procedures: Patients rated the following activities on a 0-10 scale, where 0=no difficulty and 10=extreme difficulty: walking short/long distances, negotiating close spaces, walking up/down stairs, walking up/down a hill, walking on sidewalks/ slippery surfaces/backwards, turning, and stepping over objects. The standardized evaluation also included residual limb pain rating (0=no pain, 10=worst possible pain), height and weight for calculation of body mass index (BMI), Socket Fit Comfort Score (SFCS), and the Activities-Specific Balance Confidence Scale (ABC). SFCS is a reliable and valid measure where prosthetic users are asked to rate their socket comfort on a 0-10 point scale, where 0=most uncomfortable and 10=most comfortable socket imaginable (Hanspal, 2003). The ABC is a 16-item questionnaire where patients rate how confident they are that they will not lose their balance or become unsteady with various activities; scores of 0%=no confidence, while scores of 100%=complete confidence (Powell, 1995).

Data Analysis: SPSS Statistics 22 was used to perform correlation analyses while controlling for the following covariates: age, sex, amputation level, and BMI ($p<.05$).

RESULTS

Mean age was 58.7±10.5 year and mean BMI was 29.0±4.8kg/m^2. Ambulation-activities rated most difficult included walking on slippery surfaces (6.8±3.7), walking long distances (6.5±3.2), and walking backwards (5.1±3.4). There were no correlations among residual limb pain (3.6±3.9), SFCS, or the ABC ($p>.05$). Residual limb pain was not correlated to difficulty with any of the ambulation-activities. SFCS was correlated to walking long distances (r=-.645, p=.009), turning (r=-.687, p=.005), and stepping over objects (r=-.597, p=.019). ABC was correlated to walking up stairs (r=-.820, p=.000), walking up a hill (r=-.689, p=.005), walking down a hill (r=-.624, p=.013), and walking backwards (r=-.517, p=.048).

DISCUSSION

Lack of correlation among residual limb pain rating, SFCS, and the ABC suggest these measures assess distinct constructs among older adults with LLAs. SFSC and the ABC appear to be more important factors related to self-reported ambulation-activity difficulty than residual limb pain. While exploration of SFCS is relatively novel, findings related to the ABC contribute to prior findings. Miller and Deathe found that balance-confidence, which is a strong predictor of social engagement, is a persistent problem among individuals with LLAs (2011). Perhaps interventions geared at improving socket-fit and/or balance-confidence may be effective for decreasing perceived difficulty with ambulation-activities and improving social function.

CONCLUSION

Ambulation-activity difficulties are associated with socket fit comfort and balance-confidence but not residual limb pain.

CLINICAL APPLICATIONS

Clinicians may consider inclusion of SFCS and ABC when evaluating older individuals with unilateral LLAs who express difficulty with ambulation tasks. Each of these measures may help to predict different and specific ambulation-activity difficulties, but further, longitudinal research is needed to establish causation.

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POSITIVE OUTCOMES FOLLOWING USE OF VACUUM ASSISTED SUSPENSION IN TRANS-FEMORAL AMPUTATION. A CASE SERIES

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INTRODUCTION

Individuals with transfemoral (TF) amputation may benefit from socket systems using active vacuum pumps (VAC) to create and maintain pressure at sub-atmospheric levels. Preliminary research suggests that VAC may provide a more secure suspension and improve stability, weight bearing, comfort, perception, and limb health for those with transtibial amputation. Few studies have investigated VAC when applied to the TF amputee. Currently, there are no studies examining the change in one's daily life as a result of using a VAC socket system for the TF amputee.

METHOD

Subjects: Six with TF amputation participated. All have used current prosthesis for >12 months.
Apparatus: Balance and walking capacity; activity, participation, and quality of life questionnaires.
Procedures: At baseline, testing was performed with participants ***EXISTING*** socket and questionnaires completed regarding use of ***EXISTING*** socket. Participants were measured for a flexible inner socket with polypropylene rigid frame that achieved vacuum through use of the Otto Bock Harmony E2 pump with the Evolution Aura Sheath. Two weeks later participants were tested again with ***EXISTING*** socket. Following testing the ***VAC*** socket was fit, aligned on the participant's prosthesis (knee and distal), users were instructed how to use the system, and then went home. Participants returned 2 and 4-weeks later for testing using the ***VAC*** socket. Following the 4-week test participants went back into to their ***EXISTING*** socket and were asked which socket they preferred.
Data Analysis: Means for the 2 sessions with ***EXISTING*** and the 2 sessions with the ***VAC*** socket were calculated for each participant. Data is incomplete at various time points because of deviations from testing protocol due to individual socket modifications and participant health.

RESULTS

	Age (yrs)	Since amp (yrs)	Knee	RLL (cm)	Brim Sl (cm)	Brim Sl as % of RLL
S1	61	3 (Vasc)	C-Leg	31	3.0	90.4%
S2	80	2 (Vasc)	Ttl Knee	35	4.0	88.6%
S3	68	4 (Vasc)	C-Leg	26	3.0	88.5%
S4	26	2 (CA)	C-Leg	25	2.5	90.0%
S5	41	23 (Trauma)	C-Leg	33	0.0	--
S6	30	8 (Trauma)	C-Leg	22	0.0	--

For all *EXISTING* socket was ischial containment; 2 used suction, 4 used a laynard system. RLL: residual limb length = ischial tuberosity to distal end. SI: Subischium

As seen in Table 1, a positive change was noted in all patient reported outcome measures while minimal change was noted in balance and walking abilities. 4 of the 6 participants utilized a brim that was SI. Subjective comments from participants addressed improved comfort with the ***VAC*** socket.

All who have completed the protocol have opted to ***stay in an active vacuum socket system***

DISCUSSION/CONCLUSION

In this case series, positive changes were noted using the ***VAC*** socket compared to the ***EXISTING*** socket. While the 4-week acclimation period may have been too short to result in improvements in balance or walking abilities, large improvements in perception of activity, participation and quality of life were noted supporting the use of ***VAC*** for TF amputation. These results can potentially help lead to policy change regarding reimbursement for ***VAC*** socket systems.

CLINICAL APPLICATIONS

Use of ***VAC*** sockets for TF amputation should be considered due to positive outcomes associated with activity, participation and quality of life when compared to ***EXISTING*** sockets.

TABLE 1

	Balance Sway Composite Score (Lower the better)			Overall Limits of Stability Score (Higher the better)			6-Minute Walk Test (feet)			Amputee Mobility Performance Score (Higher the better)			Activity Balance Confidence (Higher the better)			Patient Specific Functional Score (Higher the better)			Prosthesis Evaluation Questionnaire (Higher the better)		
	EXISTING	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*
S1	1.4	1.3	7%				644			37			64.3	71.3	11%	3.9	6.0	54%	5.1	6.7	31%
S2	2.1	2.1	0%	16.5	36.5	121%	481	493	2%	34	36	6%	35.9	62.2	73%	3.2	5.8	81%	4.6	6.3	37%
S3	1.5	1.8	-20%	32.0	40.5	27%	563	533	-5%	38	40	5%	35.6	60.5	70%	3.3	7.3	121%	3.7	7.3	97%
S4	1.2	1.2	0%	50.0	44.5	-11%	1477	1409	-5%	44	44	0%	37.5	49.7	33%	0.3	1.4	367%	3.1	5.9	90%
S5	1.5	1.4	7%	10.0	26.0	160%	958			42			68.8			4.3			5.4		
S6	1.1	1.1	0%	59.5	60.0	1%	1342	1402	4%	43	44	2%	87.3	91.3	5%	4.9	7.5	53%	8.3	9.3	12%

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ASSESSING STEP-BY-STEP VARIABILITY OF GROUND REACTION FORCES AS A MEASURE OF ACCOMMODATION TO PROSTHETIC INTERVENTIONS

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INTRODUCTION

Becoming accustomed to a new prosthesis or orthosis is potentially a lengthy process that may be influenced by a variety of patient- and device-specific factors. This makes it difficult in clinical practice and research to purposefully allocate accommodation times that are neither too short nor too long. As a consequence, patients may be subjected to unnecessarily repetitive optimization sessions – when device fit and alignment changes are conducted in too quick succession – or patients may have to endure prolonged periods using suboptimal devices – when optimization sessions are spaced too far apart. In research studies that involve prosthetic or orthotic interventions, measured effects of such interventions may be influenced by the allowed accommodation time, which may limit the scientific and clinical significance of results and makes it difficult to compare findings of different studies (Neumann, 2009, Geil, 2009).

This pilot study investigated the suitability of kinetics step-by-step variations within the prosthetic leg during walking as an indicator of the level of accommodation to prosthetic interventions.

METHOD

Subjects: Data of 12 subjects that had participated in a prior unrelated study (Fiedler, et. al, 2015) was re-analyzed to investigate the current hypothesis. All subjects used trans-tibial prostheses and were able to walk unaided for several minutes.

Procedure and Apparatus: Prosthesis ground reaction forces of gait were measured continuously over a 20-step sample by means of a load cell (ipecs, RTC Electronics, Dexter, MI) that was temporarily installed into subjects' existing prostheses. The plantarflexion angle of the prosthetic ankle joint was changed by 12 to 18 degrees, depending on the available range of adjustment, between walking trials.

Data Analysis: Data from the first 10 steps after such an alignment change was analyzed by comparing differences in horizontal peak forces between consecutive steps. The found differences were plotted against the step count to visualize the progression over time. An exponential function was fitted through the data points using a best-fit algorithm (Excel, Microsoft, Redmond, WA)

RESULTS

Analysis of a multitude of variables yielded R-squared values between zero and 0.58. Two representative data sets are provided to illustrate the curve trajectories (Figures 1 and 2).

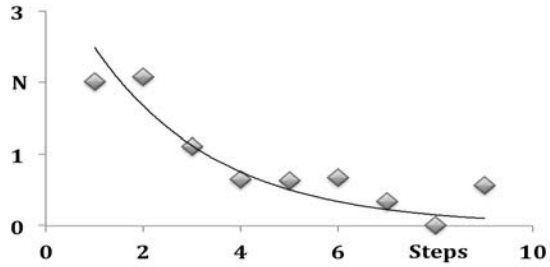

Figure 1: Step-by-step differences in peak medial ground reaction force during the first steps with a newly adjusted prosthetic foot. R^2 here is 0.44.

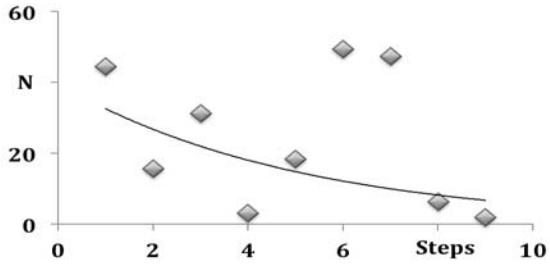

Figure 2: Step-by-step differences in peak medial ground reaction force during the first steps with a newly adjusted prosthetic foot in a different subject. R^2 = 0.19.

DISCUSSION

Our findings could not support the hypothesis that accommodation to prosthesis alignment interventions follows an exponential trajectory. Instead, the data showed a mostly random variance in step-variability across the first steps with a newly adjusted prosthesis, but also across the sample population. It may be concluded that accommodation to prosthetic interventions does not follow a general pattern, or that the here selected variable of ground reaction force differences between steps is not a suitable indicator of the level of accommodation.

CLINICAL APPLICATIONS

Our results support the notion that prosthetic fittings need to account for individual differences between patients that cannot be sufficiently described by general algorithms. Providing the proper amount of accommodation time after changing prosthetic alignments remains a domain of the involved clinician's professional judgement.

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Effect of transtibial prosthetic alignment change related to asymmetry gait pattern and fundamental motion measurement

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INTRODUCTION

To date there are no studies having assessed the relative outcomes of the final dynamic prosthetic alignment and the recommended static prosthetic alignment, and how these are related. Does the recommended static alignment influence and confirm more symmetrical gait during dynamic analysis in terms of kinematic and kinetic measurement? This project aimed to evaluate the clinical results of the final total static weight line of transtibial amputees using a 3D motion analysis system by measuring the differences between the final total static weight line and the recommended static alignment, and then comparing the effect of total static weight line changed with asymmetrical individual gait pattern in terms of kinematic and kinetic analysis.

METHOD

Subjects: Ten unilateral transtibial amputees with at least one year experience of endoskeletal transtibial prosthesis user participated in this study. All participants routinely used the same prosthetic type endoskeletal prosthesis with patellar tendon bearing socket and multi-axial prosthetic foot.

Procedures: The Vicon® motion capture System was used to collect the static and dynamic data, and the differences in gait parameters values between two groups of participants' total static weight line were analysed collectively.

Data Analysis: Six participants were included in anterior weight line group which their total static weight line were represented by GRF passing anteriorly through the knee joint while four remaining participants were defined in posterior weight line group that their total static weight line were signified GRF passing posteriorly. Symmetrical kinematic/kinetic data within subject between both limbs was compared by a general linear model for repeated measures, then those values were combined and analysed to provide mean results of all ten participants and compared the significant difference among participants in each group.

RESULTS

The sound side exerted greater effort during the gait cycle as observed from most of the kinematic and kinetic curves that represented high magnitude values when compared to the prosthetic side. The kinematic and kinetic variables showed that the joint relative angles, joint forces, and joint powers were of more symmetrical in the posterior weight line groups. However, the anterior weight line group presented more symmetrical in terms of time and distance parameters. The kinematic and kinetic data represented asymmetrical gait frequently in mid-stance and terminal stance phases.

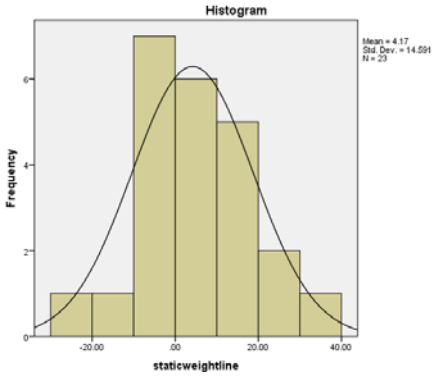

Figure1. Frequency distribution of the AP total static weight lines displacement of 10 unilateral transtibial participants

DISCUSSION

Firstly, the sound side exerts more effort during the gait cycle so asymmetrical gait may be the means by which the sound side tries to protect the residual limb. Secondly, the joint relative angles, joint forces, and joint powers are of more symmetrical parameters in the posterior weight line group. However, the anterior weight line group presents more symmetrical in term of time and distance. Lastly, the joint angles and the joint forces represent asymmetrical gait frequently in mid-stance and terminal stance phases as a consequence of the less stability of the prosthetic side during the single limb support phase.

CONCLUSION

Asymmetrical gait pattern in terms of kinematic and kinetic parameters were not influenced by how severely the final prosthetic alignment differed from the recommended static alignment in this present study results.

CLINICAL APPLICATIONS

The process of evaluating and learning 3D measurement systems could help researchers and clinicians to develop acknowledgement of the prosthetic alignment system and transtibial amputee gait clinical analysis.

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A SCOLIOSIS ANALOG MODEL FOR THE EVALUATION OF BRACING TECHNOLOGY

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INTRODUCTION

Thoracolumbar braces are commonly used to treat Adolescent Idiopathic Scoliosis (AIS). Braces serve to reduce and prevent progression of the spinal curve by applying corrective forces. Recent publications of monitored brace wear have demonstrated a braces ability to control curve progression and prevent the need for spinal fusion surgery (1). However, the magnitude and direction of these corrective forces applied by a brace to the spine remain unknown. The objective was to design and validate an analog model of a mid-thoracic single curve scoliotic deformity for quantifying structural properties of the brace and the brace force response. The model was used to investigate strap-related brace design alterations.

METHOD

Apparatus: A novel, mechanically-equivalent analog model of the AIS condition was designed and developed to simulate up to 40° of spinal correction (Figure 1). The linkage-based model was used with a biorobotic testing platform to test a scoliosis brace.

Procedures: For the purpose of the initial validation phase, the brace was tested using two types of straps (Velcro and buckle) applied in various configurations (1,2,3,4 velcro straps; 1,2,3 buckle straps) and compared to unconstrained and rigidly constrained configurations to demonstrate the capacity of the model to study brace design alterations.

Data Analysis: Measurements of the force components applied to the model and angular displacement of the linkage assembly were used to calculate the brace structural stiffness properties. Differences in mean stiffness values within and between configurations were compared using a one-way ANOVA and ranked using Tukey's post hoc test.

RESULTS

Calculated stiffness (N/deg) was expressed as a resistive force (N) relative to the angular change (Deg) of the linkages (Table 1). Either strap type significantly increased the stiffness values relative to the unconstrained configuration. An optimal brace radial stiffness was achieved with three Velcro straps, i.e., no significant stiffness gained by adding a fourth strap. For the buckle straps, no significant stiffness gain occurred when more buckle straps were added.

DISCUSSION

Structural properties provide a means to compare bracing technology and better understand design features. The testing of design alterations, i.e., variable strap configurations, show a measureable difference in brace force response and structural Properties between each configuration. Also, interpretation of the measured force components revealed that the brace applied inward and upward forces to the spine.

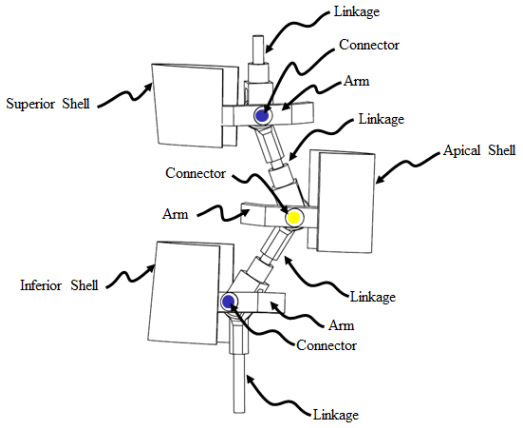

Figure 1. Schematic representation of the Scoliosis Analog Model prior to attachment to the biorobotic testing platform and prior to application of the brace.

Configurations (No. of straps in brackets)	RADIAL STIFFNESS (N/DEG)	AXIAL STIFFNESS (N/DEG)
(1) (2) (3) (4) Velcro Straps	(1)1.3 (2)2.4 (3)3.5 (4)3.6	(1)17.6 (2) 23.3 (3) 27.2 (4)29.3
(1) (2) (3) Buckle Straps	(1)2.4 (2)2.8 (3)3.8	(1)11.8 (2)15.3 (3)18.6
No Strap	0.0	0.9
Rigid Cable	10.9	153.8

Table 1. Mean Radial and Axial Stiffness Values.

CONCLUSION

A novel scoliosis analog model and testing assembly were developed to provide first time measures of the forces applied to the spine by a thoracolumbar brace. In addition to quantifying brace structural properties, this test assembly could be used as a design and testing tool for scoliosis brace technology.

CLINICAL APPLICATIONS

This Scoliosis Analog Model will provide a platform to test and quantify the forces generated by a scoliosis brace which will allow for improvements in brace design and efficacy.

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USING PROXIMITY SENSORS TO DIGITALLY MEASURE BI-PLANAR ALIGNMENT ANGLES OF PYRAMID ADAPTORS IN LOWER LIMB PROSTHETICS

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INTRODUCTION

In the US in 2005, there were approximately 1.04 million people with lower limb loss. By 2050 this number is expected to increase to 2.34 million (Ziegler-Graham, 2008). With this increase, more people will need lower limb prosthetics and prosthetic alignments.

To date, there is no standardized way to quantify the alignment of prosthetic pyramid adaptors outside of estimation and counting set screw rotations. The lack of clear, repeatable alignment angles limits the efficiency of clinical practice and research protocols (Neumann, 2009). The goal of this project was to develop a device that digitally measures the bi-planar alignment angles of pyramid adaptors. This device was designed to fit the standard pyramid adaptor so that it would neither obstruct adaptor movement nor include any internal electrical components.

METHOD

Proximity sensors that output voltages in response to magnetic field strength using the Hall Effect were investigated to devise a touchless sensor system (Hall, 1879). The procedure was divided into three tasks: 1) Determine the best sensor position by investigating the relationship between sensor placement and magnetic field strength at various alignment angles; 2) Determine the conversion between sensor voltage (V) and the linear distance (mm) between them; 3) Develop a final prototype.

RESULTS

Sensor placement on the outside of the pylon directly in front of the middle of the North Pole of the magnet yielded the maximum magnetic field response. A spherical magnet provided the most uniform field for both bi-planar sensors. The voltage-to-distance conversions with and without the pylon were approximated by a fourth order polynomial equation. The pylon angle was then found using a trigonometric equation. Hall Effect Sensors (MLX90215, Digi-Key Electronics) were chosen to be placed on the outside of the pylon in bi-planar directions using an additive manufactured clip. A magnet was placed on the pyramid adaptor. An LCD board displayed the bi-planar alignment angles (Figure 1) and was housed in an acrylic case with two calibration buttons.

DISCUSSION

To date there is no commercially available device that digitally displays pyramid adaptor alignment angles using proximity sensors. Other tools such as the LASAR posture (Blumentritt, 1997) and the "smart pyramid" (Kobayashi, 2013) measure the effects of alignment changes but not the direct angle changes that are important for quality control and documentation.

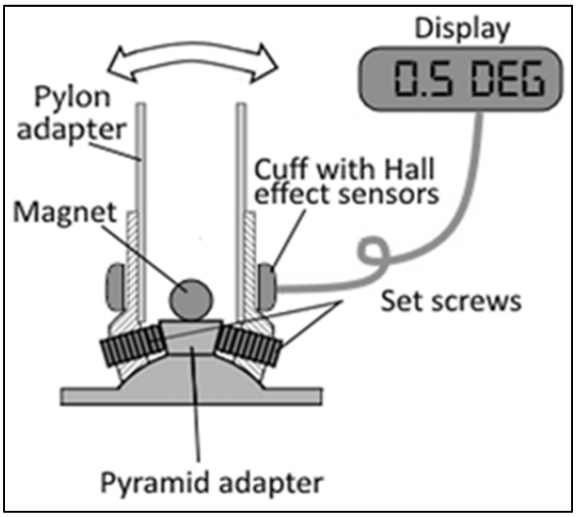

Figure 1. Principle of alignment angle measurement

Further evaluation studies and field tests on the device are planned. Additional work can be done to provide users with angle readouts on their hand held devices.

CONCLUSION

A device to measure and display the bi-planar alignment angles of pyramid adaptors will allow practitioners to more easily and accurately align lower limb prostheses, providing patients with clearly defined, repeatable adjustment to their prosthesis.

CLINICAL APPLICATIONS

With an increased amount of lower limb prosthetics necessary in the years to come, innovations like this will help decrease the number of revisits to clinics for prosthetic readjustment, therefore improving patient quality of care and reducing health care costs.

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Comparing the Difficulty of Maintaining Rhythm on Bass Drum and Hi-Hat Pedals Using Prostheses and Drum Set Adjustments

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INTRODUCTION

Challenges arise for lower limb amputees when playing the bass drum and hi-hat pedals on drum sets. Each individual with a lower limb amputation must develop a method that works best when playing drum set: building an extension$_1$ or using only one pedal$_2$. This study compared different such strategies to find the easiest method of playing drum set for prosthesis-users. It was hypothesized that a rearrangement of the drum set to allow one foot to control both pedals (Toe-heel model: Figure 1) would provide a consistency of rhythm closer to the consistency of playing with two able bodied feet than the rhythm produced using pseudo-prostheses.

METHOD

Subjects: Subjects were recruited that were non-prostheses users, able to wear a pseudo-prosthesis, and had no severe hearing loss/ cognitive impairment.

Apparatus: A bass drum pedal (P930, Pearl Corporation, Nashville, TN) and a bass drum (VBL925P/C232, Pearl Corporation, Nashville, TN) were used with a hi-hat stand and pedal (9607DL, Kmc Music Inc). Koss Ear Buds were used to listen to the Mobile Metronome Application (Gabriel Simoes). Audacity 2.1.0 (open source) was used to record each trial and to see the time that each beat occurred. Two different pseudo-prostheses were used in certain interventions to test different methods.

Procedures: Four setups were used at both 100 beats per minute (bpm) and 200bpm to create eight interventions: Standard (A), Below-Knee (BK) pseudo-prosthesis (B), Above-Knee (AK) pseudo-prosthesis (C), and the Toe-heel model (Figure 1) (D). Each intervention was put in a randomized order for each subject and tested by playing a 24 beat pattern.

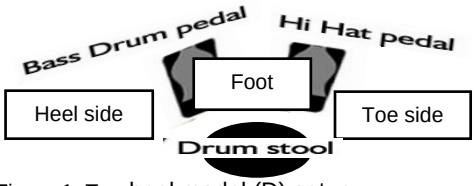

Figure 1: Toe-heel model (D) setup

Data Analysis: The average deviation between the metronome and played beats was calculated for all trials. The resulting values represent the accuracy of the rhythm compared to the metronome. Post-hoc comparisons were undertaken as appropriate. A critical alpha of 0.05 seconds was defined prior to data collection. The comparison was done by 2-way (condition x bpm) repeated measures analysis of variance (ANOVA) in SPSS (IBM, version 22).

RESULTS

Seven subjects completed the protocol. Condition, the main effect, was found to be significant (p=0.006), but neither the main effect of bpm (p=0.119) nor the interaction effect of condition and bpm (p=0.350) were significant at the 0.05s level. Post-hoc comparisons showed that only condition C (AK pseudo-prosthesis) significantly varied from the other conditions (Figure 1). The mean difference in the steadiness of rhythm against the metronome was +0.069s when compared to condition A, +0.039s when compared to condition B, and +0.061s when compared to condition D (Figure 2). Other differences between conditions were not significant at the 0.05s level.

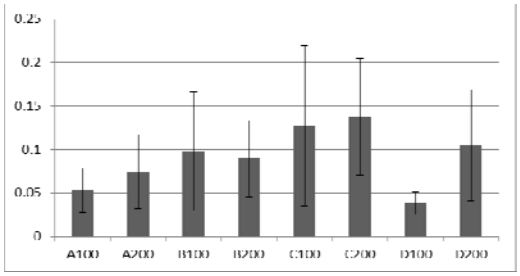

Figure 2. Mean and Standard Deviation in Seconds for each Testing Condition

DISCUSSION

The hypothesis was confirmed for the AK pseudo-prosthetic attachment because it was less consistent than the accuracy of the toe-heel model. The rhythm maintained with the toe-heel model was not significantly different than the standard of playing with two typical feet. The hypothesis could not be confirmed for the BK pseudo-prosthesis.

Among the limitations of this study was the small sample size and the use of able-bodied subjects. It is recommended to confirm our findings with a follow-up study that addresses those limitations.

CONCLUSION

The toe-heel model on the drum set seems to be recommendable for individuals who use an AK prosthesis because the toe-heel model would maintain better rhythm than the prosthesis.

CLINICAL APPLICATIONS

Adapting to activities of daily life after limb loss is important for the successful rehabilitation and the attainment of a normal quality of life. Our findings provide evidence on the most appropriate adaptation strategy for people who play the drum set.

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EFFECTIVENESS OF STANCE-CONTROL-ORTHOSES COMPARED TO ANKLE-FOOT-ORTHOSES: A PILOT STUDY

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INTRODUCTION

Spinal cord injury (SCI) affects both sensory and motor signals; potentially causing abnormal gait and sensory impairments (Kirshblum et al., 2011). Patients with neuromuscular impairment, like lower level SCI, are commonly prescribed lower limb orthoses to promote a functional walking pattern. Specific examples of orthoses prescribed to patients with SCI may include ankle-foot-orthosis (AFO), knee-ankle-foot orthosis (KAFO), or a stance control orthosis (SCO). The design chosen must find a balance between assisting with mobility and maintaining joint integrity while minimizing the burden of use for the wearer (e.g. device bulk, energetic costs, etc.).

The purpose of this study is to investigate how the relative benefits and drawbacks associated with the more conservative approach of using AFOs versus the potential benefit of knee control with the more complicated SCO would affect the gait of someone with incomplete SCI. Relevant clinical outcome measures were used to increase reproducibility by practitioners, therefore making our study more clinically relevant.

METHOD

Subject: 25 year old female (5'2" & 110lbs), with no gait impairments was used to provide baseline data for a person with an incomplete L1 spinal cord injury. The subject with SCI (incomplete at L1 level) has been recruited but data has not yet been collected. *Fabrication*: The SCI and control subject were evaluated by a certified orthotist and a Becker stance-control-orthosis was customized to the fit and a custom solid AFO was fabricated and fitted.

Apparatus: The 2-minute walk test and Physiological cost index (PCI) were the two primary outcome measures. Six retroreflective markers were applied bilaterally to the following landmarks: apex of the lateral malleoli, ASIS, and PSIS. Markers were tracked via a twelve camera motion capture system (Vicon Inc., Oxford, UK). A gait real time analysis interactive lab (GRAIL, Motek Medical B.V., NL) system was used which consisted of a 50 cm x 200 cm, split- belt treadmill synchronized with a motion capture system that allows for self-paced walking by adjusting belt speed to keep the person in the middle of the treadmill, and virtual reality immersion through a 180 degree, 3D projection screen. The subject was attached to a safety harness to prevent injury. The PCI was calculated by (beats/m) = (walking heart rate (beats/min) – resting heart rate (beats/min)) / walking speed (m/min).

Procedures: Three trials were taken, one with no orthoses, one with an AFO, and one with SCO. The two minute walk test was performed using the self-paced treadmill, and person's heart rate was taken before the test began and 30 seconds before the test ended for the PCI.

Data Analysis: The minimum detectable changes for the two minute walk test (±42.5m) (Bohannon et al., 2015) and the PCI (±.070 b/m) (Hagberg et al., 2011) were compared to demonstrate if there was a clinically relevant difference between the device conditions.

RESULTS

The results for the control subject showed that with no orthotic intervention, the subject walked 284m in the 2-minute walk test and scored .38 b/m on the PCI. With an AFO, the subject walked 209m and scored .48b/m on the PCI. Using SCO the subject walked 185.7m and scored .57b/m on the PCI.

DISCUSSION

The differences regarding the PCI and 2-minute walk test between the baseline and device conditions were greater than the minimum detectable change indicating that wearing the device increased energetic costs for the control subject. This could be due to this control subject being a healthy adult and is not indicated for any assistive device. The benefit to someone with a SCI will become clearer once additional data has been collected on people with SCI.

CONCLUSION

This pilot study demonstrated the validity of our methodology and provides baseline data to compare to a larger sample containing people with low level incomplete SCI.

CLINICAL APPLICATIONS

This study demonstrates how clinically available outcome measures can be used to determine if the patient will benefit from SCO or AFOs.

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American Academy of Orthotists & Prosthetists
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March 9-12th, 2016

An Improved Design for Transtibial Prosthesis Emulating Devices

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INTRODUCTION

Advancements is prosthetic designs could be accelerated through the use of a Prosthesis Emulating Device.

A Prosthesis Emulating Device (PED) is a special orthosis used by people without amputation that replicates the biomechanics of ambulating with an amputation. Unlike other emulators, which utilize a cast boot in conjunction with prosthetic componentry, our emulator will utilize a pseudo-socket design that consists of a plastic clamshell that encapsulates the shank of the lower limb. The distal end is opened to prevent load bearing through the foot-ankle complex and thus requires energy transfer to occur through the soft-tissues of the shank, similar to the biomechanics of controlling a transtibial prosthesis.

The purpose of this study was to create a PED to compare to uni-lateral transtibial amputee gait.

METHOD

Subjects: One able-bodied female (25 y/o, 74.8 kg, 1.75 m) and one female with a uni-lateral transtibial amputation (19 y/o, 60 kg, 1.65 m) has completed to his IRB approved study.
Apparatus: The Gait Real-time Analysis and Interactive Laboratory (Motek Medical, Amsterdam, NL) consisted of a 50 cm x 200 cm split-belt treadmill with force sensors mounted underneath both belts to measure ground reaction forces, and a 180 degree projection screen that corresponds with the speed of the treadmill to immerse the subject in a virtual reality. A lower-limb, 26 marker Human Body Model (Motek Medical, Amsterdam, NL) and a twelve-camera motion capture system (Vicon Motion Systems, Oxford, UK) will record limb kinematics (100 Hz). D-Flow control software suite 3.28.1 (Motek Medical, Amsterdam, NL) was used to define the sensory input provided to the subject. A safety harness was attached to the subjects to prevent injury.
Procedures: The participant walked at a self-selected speed wearing their typical footwear without the PED. For the second condition, the participant donned the PED uni-laterally and a shoe lift was used on the contralateral side to account for the height difference by adding a prosthetic foot (Pacifica LP, Freedom Innovations, Irvine, CA). After a habituation session which allowed the participant to acclimate to the devices, the subject walked at self-selected speed. Data on limb kinematics, kinetics, EMG, and video were collected.
Data Analysis: The Gait Offline Analysis Tool (Motek Medical, Amsterdam, NL) was used to calculate joint powers and GRF in the A-P direction. Twenty strides were time normalized to 100 datapoints and then averaged together per limb and per condition.

RESULTS

The minimum GRF in the A-P direction of the PED when normalized for bodyweight was 1.5 N/kg. The minimum GRF in the A-P direction of the transtibial amputated side when normalized for bodyweight was 1.08 N/kg. The minimum GRF in the A-P direction of the control when normalized for bodyweight was 2.2 N/kg.
PED peak ankle power was more similar to ankle power of the amputated limb in the participant with amputation (Figure 1).

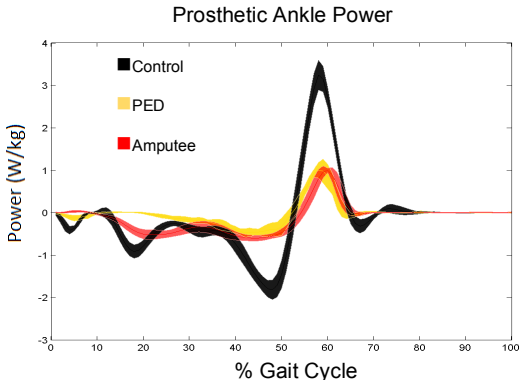

Figure 1. Ankle power is diminished during pre-swing (50-62% of gait cycle) in both the subject with amputation and PED conditions when compared to the control.

DISCUSSION

The GRF of PED trials during pre-swing phase of gait (50-62%) displays decreased power absorption which correlates with a decrease in propulsive forces seen in transtibial amputee gait. (Silverstein, 2011)

Ankle power during pre-swing of the PED trial was decreased by over 300% compared to the control trial, similar to the peak ankle power of the transtibial amputee during pre-swing.

CONCLUSION

The PED produces gait characteristics similar to gait with a transtibial amputation particularly the residual limb ankle power during pre-swing and propulsive GRF during pre-swing.

CLINICAL APPLICATIONS

This improved PED can be utilized in future research to improve design of prosthetic components.

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THE EFFECT OF PROSTHETIC FEET ON BOATS

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INTRODUCTION

Sailing is a feasible but under-rated hobby for lower limb amputees and disabled individuals who wish to sail recreationally and professionally. Promoting sailing can help address problems of reduced physical activity in this population. The boats used for adaptive sailing are reduced to a small cockpit for the individual with many pedals, switches and levers to allow full control of the vessel while remaining seated and stationary. Use of larger or non-modified vessels, however, remains challenging.

Mobility and balance aboard boats is of great importance for operating and maintaining a boat. [1] Having a prosthetic foot with the greatest ability to move about and balance while boating is crucial for the safety and comfort of an amputee on the water. [2] On a boat, demand for balancing in the A-P and M-L directions is dramatically increased compared to on normal ground. Therefore, a prosthetic foot that is more effective for an individual on normal ground for gait and balance may not be as effective as another prosthetic foot aboard a boat, such as a peg-leg.

This study is exploratory and focuses on boats, which have not been adapted for an individual, in order to further open up sailing as a feasible activity for persons with lower limb loss. The aim is to compare center of mass (COM) displacement in unilateral trans-tibial amputees when using a peg leg (or peg-leg substitute) with other prosthetic foot options aboard a boat.

It was hypothesized that the Peg-Leg foot provides a more stable standing and balancing on an ocean vessel compared to the person's regular prosthetic foot.

METHOD

Subjects: Person with trans-tibial limb loss, who were using a modular prosthesis for ambulation were recruited for this pilot study.

Apparatus: A questionnaire assessing the experience of subjects as it relates to boating was administered. COM displacements were recorded using an iPecs mobile gait lab (RTC Electronics, Frazer, MI). Data collection took place on a 24-foot boat moored on a local river.

Procedures: The subject's prosthesis was modified by installing the iPecs module into the existing structure. The existing foot was replaced by a rubber stomper foot (Stomper Products, SPS) for part of the data collection. The subject was asked to stand still for one minute once on solid ground and once on the boat. The procedure was repeated after feet were changed.

Data Analysis: The continuously collected horizontal ground reaction force data were plotted and interpreted using Excel (Microsoft, Redmond, WA). The total length of the plotted trajectory of the horizontal ground reaction vector over the one minute intervals was computed and used for comparison.

Statistical Test; A 2x2 ANOVA was conducted to compare main effects between feet and between standing surfaces, as well as the interaction effect.

RESULTS

Data of the first subject is presented here. The subject was a 54-year-old former member of the US NAVY, who underwent traumatic limb loss 18 years ago. His standard prosthesis consisted of a total surface bearing socket with liner suspension and an energy – storage-and-return foot.

The trajectory of the horizontal ground reaction force vector over the course of one-minute-standing trials was generally longer with the peg leg than the conventional foot (Figure 1).

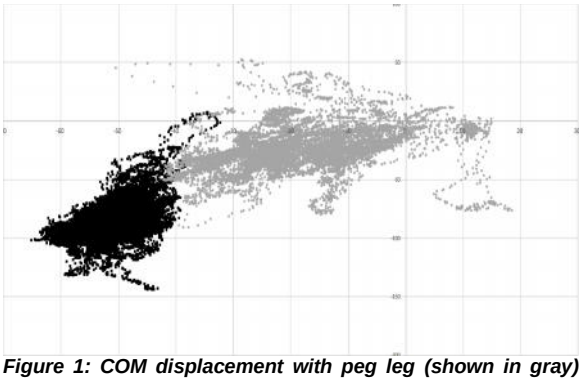

Figure 1: COM displacement with peg leg (shown in gray) compared to COM displacement with normal prosthetic foot (shown in black) aboard a 24 ft boat.

DISCUSSION

The plotted data indicate a substantial difference in COM displacement when using different feet on a boat. The COM trajectory wearing the normal prosthetic foot was more concentrated and shorter in length than the COM trajectory while wearing the peg leg suggesting that a peg leg does not decrease the effect of boat motions on the COM trajectory relative to a normal prosthetic foot.

CONCLUSION

A regular prosthetic foot may have advantages over a peg leg device when used for ambulation and balance on boats.

CLINICAL APPLICATIONS

Use of dedicated prosthetic feet can have effects on the standing and walking stability of persons with limb prostheses on boats. In order to facilitate the safe engagement in boating as a health leisure activity, foot selection should be carefully considered.

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1 2 3 PATENT

Christopher Joel Stunz
Eastern Michigan University

INTRODUCTION

This poster presentation will simplify the United States patenting process for new inventors or contributors of the orthotic and prosthetic field. The presentation will utilize published works, United States Patent and Trademark Office recommendations, and various resources to educate the reader. The poster will provide graphs, guided steps, handouts, and related material to assist the visitor. The author will include relevant information about timelines, legal rights, and any related content to assist the interested personnel.

METHOD

Cross referencing information from publications and websites will be the primary focus of the methodology. Since this will be unconventional to the general poster presentation no specific methods or data will be excluded from publication unless found to be false.

DISCUSSION

It is unquantifiable to determine the number of people who have had ambition to provide contributions for the field of O&P. Many people have been scared away from contribution due to the headache of patenting. My goal is to help prospective inventors protect and patent their contributions through simplifying the understanding of the patenting process.

CLINICAL APPLICATIONS

This will provide prospective contributors of the O&P field smoother transition from idea to creation.

A Qualitative and Quantitative Comparison of CAD/CAM and Plaster-Casted TLSOs: A Case Study

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INTRODUCTION

Manual plaster casting has been the preferred method of shape capture for prosthetists and orthotists (Sankar et al., 2007). With the introduction of Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM), questions have been raised of this procedure's efficacy of treatment when compared to the well-established manual method for the fabrication of TLSOs. In those studies which compared the manual method to CAD/CAM, little definition is given to the casting or scanning procedures, or to the amount and location of modifications which occurred. Furthermore, most are lacking in qualitative or quantitative outcome measures.

Most often studies will state that modifications to plaster molds were made in the "conventional manner," without any definition as to what this involves (Raschke et al., 1990; Wong et al., 2005). Reproducibility of these studies can be called into question as there can be different conventional modifications between practitioners. In those studies that compared CAD/CAM to plaster casted TLSOs, there is an unaddressed confounding variable that could have drastic effects on the results. Sankar et al. (2007) did not define these, and found no significant difference between in-orthosis curve corrections for Adolescent Idiopathic Scoliosis.

It is the purpose of this study to determine which fabrication method is more comfortable for patients between the CAD/CAM and plaster casting methods for the fabrication of TLSOs by comparing patient preference in comfort and measurements in circumferences and Medial-Lateral (ML) width at the chest, waist, and ASIS levels.

METHOD

Subjects: One anticipated male or female subject, between the ages of 21 and 30, with no diagnosed medical condition or spinal deformity. Preferred weight is under 180 pounds and height under 6 feet.

Apparatus: Two questionnaires; A measuring tape; ML gauge.

Procedures: At evaluation prior to casting of the subject, the baseline ML and circumference measurements are to be taken at the xiphoid, waist, and Anterior Superior Iliac Spine (ASIS) levels. During casting and scanning, the subject should be standing in an erect posture, knees slightly flexed, and hands holding stands for support on either side. The negative models from both methods will be aligned the same way. The same specific amounts of build-ups and reductions will be applied on the CAD/CAM and plaster models. The subject will be randomly assigned to wear one of the orthoses for 12 hours a day, for 5 days, and then complete Questionnaire 1. After a one week break, the subject will then wear the second orthosis for the same time period. Upon completion, the subject will fill out Questionnaire 1 again. The comprehensive Questionnaire 2 will be completed as well.

Data Analysis: The answers to the two questionnaires will be analyzed to determine which is most comfortable. Tests for significant differences between baseline measurements and the two TLSOs will be measured for comparative statistical analysis at the same locations as baseline.

RESULTS

Due to the change in venue of our program at our school, completion of this study should be by December 2015.

DISCUSSION

The results could reveal that the CAD/CAM modifications are less comfortable than the plaster method or vice versa, or that there is no difference between the methods. We anticipate our results will give qualitative and quantitative data on which casting method produced the most comfortable TLSO through the elimination of a possible confounding variable unaddressed by previous studies.

CLINICAL APPLICATIONS

Through the comparisons, the results may show which of these methods has more or less comfort, or no difference between them. Clinicians will be able to better choose within their current environment between these two methods for providing TLSOs to their patients. Furthermore, defining these techniques enhances the understanding of a growing area of the orthotics field allowing for positive effects on future patient outcomes.

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A SCOLIOSIS ANALOG MODEL FOR THE EVALUATION OF BRACING TECHNOLOGY

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INTRODUCTION

Thoracolumbar braces are commonly used to treat Adolescent Idiopathic Scoliosis (AIS). Braces serve to reduce and prevent progression of the spinal curve by applying corrective forces. Recent publications of monitored brace wear have demonstrated a braces ability to control curve progression and prevent the need for spinal fusion surgery (1). However, the magnitude and direction of these corrective forces applied by a brace to the spine remain unknown. The objective was to design and validate an analog model of a mid-thoracic single curve scoliotic deformity for quantifying structural properties of the brace and the brace force response. The model was used to investigate strap-related brace design alterations.

METHOD

Apparatus: A novel, mechanically-equivalent analog model of the AIS condition was designed and developed to simulate up to 40° of spinal correction (Figure 1). The linkage-based model was used with a biorobotic testing platform to test a scoliosis brace.

Procedures: For the purpose of the initial validation phase, the brace was tested using two types of straps (Velcro and buckle) applied in various configurations (1,2,3,4 velcro straps; 1,2,3 buckle straps) and compared to unconstrained and rigidly constrained configurations to demonstrate the capacity of the model to study brace design alterations.

Data Analysis: Measurements of the force components applied to the model and angular displacement of the linkage assembly were used to calculate the brace structural stiffness properties. Differences in mean stiffness values within and between configurations were compared using a one-way ANOVA and ranked using Tukey's post hoc test.

RESULTS

Calculated stiffness (N/deg) was expressed as a resistive force (N) relative to the angular change (Deg) of the linkages (Table 1). Either strap type significantly increased the stiffness values relative to the unconstrained configuration. An optimal brace radial stiffness was achieved with three Velcro straps, i.e., no significant stiffness gained by adding a fourth strap. For the buckle straps, no significant stiffness gain occurred when more buckle straps were added.

DISCUSSION

Structural properties provide a means to compare bracing technology and better understand design features. The testing of design alterations, i.e., variable strap configurations, show a measureable difference in brace force response and structural Properties between each configuration. Also, interpretation of the measured force components revealed that the brace applied inward and upward forces to the spine.

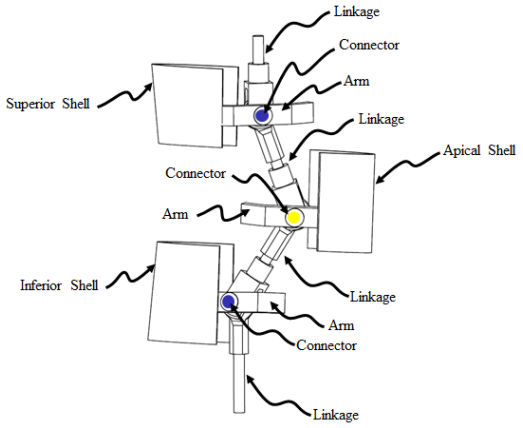

Figure 1. Schematic representation of the Scoliosis Analog Model prior to attachment to the biorobotic testing platform and prior to application of the brace.

Configurations (No. of straps in brackets)	RADIAL STIFFNESS (N/DEG)	AXIAL STIFFNESS (N/DEG)
(1) (2) (3) (4) Velcro Straps	(1)1.3 (2)2.4 (3)3.5 (4)3.6	(1)17.6 (2) 23.3 (3) 27.2 (4)29.3
(1) (2) (3) Buckle Straps	(1)2.4 (2)2.8 (3)3.8	(1)11.8 (2)15.3 (3)18.6
No Strap	0.0	0.9
Rigid Cable	10.9	153.8

Table 1. Mean Radial and Axial Stiffness Values.

CONCLUSION

A novel scoliosis analog model and testing assembly were developed to provide first time measures of the forces applied to the spine by a thoracolumbar brace. In addition to quantifying brace structural properties, this test assembly could be used as a design and testing tool for scoliosis brace technology.

CLINICAL APPLICATIONS

This Scoliosis Analog Model will provide a platform to test and quantify the forces generated by a scoliosis brace which will allow for improvements in brace design and efficacy.

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POSITIVE OUTCOMES FOLLOWING USE OF VACUUM ASSISTED SUSPENSION IN TRANS-FEMORAL AMPUTATION. A CASE SERIES

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INTRODUCTION

Individuals with transfemoral (TF) amputation may benefit from socket systems using active vacuum pumps (VAC) to create and maintain pressure at sub-atmospheric levels. Preliminary research suggests that VAC may provide a more secure suspension and improve stability, weight bearing, comfort, perception, and limb health for those with transtibial amputation. Few studies have investigated VAC when applied to the TF amputee. Currently, there are no studies examining the change in one's daily life as a result of using a VAC socket system for the TF amputee.

METHOD

Subjects: Six with TF amputation participated. All have used current prosthesis for >12 months.
Apparatus: Balance and walking capacity; activity, participation, and quality of life questionnaires.
Procedures: At baseline, testing was performed with participants ***EXISTING*** socket and questionnaires completed regarding use of ***EXISTING*** socket. Participants were measured for a flexible inner socket with polypropylene rigid frame that achieved vacuum through use of the Otto Bock Harmony E2 pump with the Evolution Aura Sheath. Two weeks later participants were tested again with ***EXISTING*** socket. Following testing the ***VAC*** socket was fit, aligned on the participant's prosthesis (knee and distal), users were instructed how to use the system, and then went home. Participants returned 2 and 4-weeks later for testing using the ***VAC*** socket. Following the 4-week test participants went back into to their ***EXISTING*** socket and were asked which socket they preferred.
Data Analysis: Means for the 2 sessions with ***EXISTING*** and the 2 sessions with the ***VAC*** socket were calculated for each participant. Data is incomplete at various time points because of deviations from testing protocol due to individual socket modifications and participant health.

RESULTS

	Age (yrs)	Since amp (yrs)	Knee	RLL (cm)	Brim Sl (cm)	Brim Sl as % of RLL
S1	61	3 (Vasc)	C-Leg	31	3.0	90.4%
S2	80	2 (Vasc)	Ttl Knee	35	4.0	88.6%
S3	68	4 (Vasc)	C-Leg	26	3.0	88.5%
S4	26	2 (CA)	C-Leg	25	2.5	90.0%
S5	41	23 (Trauma)	C-Leg	33	0.0	--
S6	30	8 (Trauma)	C-Leg	22	0.0	--

For all *EXISTING* socket was ischial containment; 2 used suction, 4 used a laynard system. RLL: residual limb length = ischial tuberosity to distal end. SI: Subischium

As seen in Table 1, a positive change was noted in all patient reported outcome measures while minimal change was noted in balance and walking abilities. 4 of the 6 participants utilized a brim that was SI. Subjective comments from participants addressed improved comfort with the ***VAC*** socket.

All who have completed the protocol have opted to ***stay in an active vacuum socket system***

DISCUSSION/CONCLUSION

In this case series, positive changes were noted using the ***VAC*** socket compared to the ***EXISTING*** socket. While the 4-week acclimation period may have been too short to result in improvements in balance or walking abilities, large improvements in perception of activity, participation and quality of life were noted supporting the use of ***VAC*** for TF amputation. These results can potentially help lead to policy change regarding reimbursement for ***VAC*** socket systems.

CLINICAL APPLICATIONS

Use of ***VAC*** sockets for TF amputation should be considered due to positive outcomes associated with activity, participation and quality of life when compared to ***EXISTING*** sockets.

TABLE 1

	Balance Sway Composite Score (Lower the better)			Overall Limits of Stability Score (Higher the better)			6-Minute Walk Test (feet)			Amputee Mobility Performance Score (Higher the better)			Activity Balance Confidence (Higher the better)			Patient Specific Functional Score (Higher the better)			Prosthesis Evaluation Questionnaire (Higher the better)		
	EXISTING	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*	*EXISTING*	*VAC*	*% Change*
S1	1.4	1.3	7%				644			37			64.3	71.3	11%	3.9	6.0	54%	5.1	6.7	31%
S2	2.1	2.1	0%	16.5	36.5	121%	481	493	2%	34	36	6%	35.9	62.2	73%	3.2	5.8	81%	4.6	6.3	37%
S3	1.5	1.8	-20%	32.0	40.5	27%	563	533	-5%	38	40	5%	35.6	60.5	70%	3.3	7.3	121%	3.7	7.3	97%
S4	1.2	1.2	0%	50.0	44.5	-11%	1477	1409	-5%	44	44	0%	37.5	49.7	33%	0.3	1.4	367%	3.1	5.9	90%
S5	1.5	1.4	7%	10.0	26.0	160%	958			42			68.8			4.3			5.4		
S6	1.1	1.1	0%	59.5	60.0	1%	1342	1402	4%	43	44	2%	87.3	91.3	5%	4.9	7.5	53%	8.3	9.3	12%

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POTENTIAL BARRIERS FOR THE USE OF HYDROTHERAPY IN THE REHABILITATION OF LOWER-LIMB AMPUTEES

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INTRODUCTION

A large part of the field of orthotics and prosthetics focuses on a patient's healing and his or her adaptation to a new way of life with a prosthesis or an orthosis (Munin, 2001). In many instances the ultimate goal is assisting patients with the transition from poor ambulation to normal function (Munin, 2001). One adjunctive therapy used to facilitate this transition is hydrotherapy (Mooventhan & Nivethitha, 2014). Hydrotherapy is an effective rehabilitation modality that could provide significant assistance in the rehabilitation of those with amputation, but its use is not documented well in the literature. Why is it not used more often? The goals of this project were to identify potential barriers to adoption by examining the literature to ascertain possible reasons for low use (cost, effectiveness, availability) and offer recommendations for exploring increased use where appropriate.

METHOD

We obtained information regarding the attributes of hydrotherapy through numerous peer-reviewed journals and databases. We then evaluated current water-resistant prosthesis designs to determine whether they would be appropriate for use in hydrotherapy. To address cost, availability, and effectiveness, we will contact practicing physical therapists and hydrotherapy clinics to gain more specific information about hydrotherapy and integrative therapies, and typical rehabilitation time frames. This information will be gathered through interview-style surveys. In order to achieve an adequate sample size, we intend to survey as many hydrotherapy practitioners in the Great Lakes region as possible.

RESULTS

At this time we are still in the process of gathering data. Once we have completed our surveys and compiled enough literature we will report on the following: the mean cost of hydrotherapy, the availability of hydrotherapy facilities, the rehabilitation timeline for patients of hydrotherapy, and the availability of prosthetic devices appropriate for use in hydrotherapy. We may have additional data to report should the study yield other potential barriers to the adoption of hydrotherapy as a rehabilitation technique for amputees.

DISCUSSION

Currently, we do not have results to discuss. Once we have gathered and analyzed our data, we will discuss the implications of our results. We will also discuss any complications we experience during our study, and ways in which we can improve.

Photograph of hydrotherapy

CONCLUSION

Our conclusion will be drawn from a comparison of our results to similar data about current rehabilitation and therapy practices. Through this study, we hope to reveal whether hydrotherapy could be a worthwhile rehabilitation practice for the field of orthotics and prosthetics. By extension, we also hope to point out the potential barriers that could be preventing the expansion of hydrotherapy into a viable therapy practice for amputees so they may be addressed.

CLINICAL APPLICATIONS

The results of our study will identify potential areas for improvement in order to push hydrotherapy to become a viable therapy choice for people with a lower-limb amputation. This would then allow different demographics to reap the benefits associated with hydrotherapy and other related practices.

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February 18 - 21, 2015

FPTH14

"THE ATOMIZATION OF ALGINATE AS AN ALTERNATIVE PROCEDURAL METHOD OF APPLICATION FOR CASTING."

SMITH, G.D.
EASTERN MICHIGAN UNIVERSITY ORTHOTICS & PROSTHETICS MASTERS PROGRAM

INTRODUCTION

Development of an alternative procedural method for alginate casting by using an automotive grade gravity-fed conventional spray gun for capturing accurate and detailed impressions. This method is achieved through spraying alginate directly onto the skin in layers. The development of the procedural application leads to a method of casting which uses the material more efficiently while not compromising detail. This method is ideal for use in the development of cosmetic prosthetics, development of residual limb teaching aids for the field of prosthetics education, and further exploration and economic use of alginate casting material.

METHOD

The application of alginate in a propellant aerosol form requires the use of Alga-Safe® Breeze which is a liquid form of alginate typically mixed 1 part alginate to 5 parts distilled water heated to 80.0°F/27.0°C for traditional pouring application. For applying with a gravity-fed conventional spray gun the ratio and temperature of the alginate must be altered to 1 part alginate to 5.5 parts distilled water heated to 77.5°F/25.3°C increasing the workable pot-life of the material and lengthening the cure time of the material once applied. A compressor and a conventional spray gun are necessary for the application. The regulated PSI of the compressor must be set to the range of 30-35 PSI prior to spraying the alginate. The 5.5 parts distilled water is heated to 77.5°F/25.3°C and poured into the pot of the spray gun, the 1 part Alga-Safe® Breeze alginate (measured prior) is gently and continuously poured into the pot while stirring the distilled water/alginate mixture continuously for 30-40 seconds or until completely incorporated, but not more than 2 minutes. The application of alginate is sprayed 4-6inches from the surface of the prepared skin while making continuous back and forth passes to gradually build up the material on the surface. The pot-life of the material is increased to 20 minutes providing adequate time to cover the desired area. Once completely covered, cotton is imbedded into the material by gently pressing the cotton into the external shell of the alginate cast. Then the curing cast is wrapped in fiberglass gauze while still on the skin providing stability to the cast and preventing distortions when the cast is removed and back-filled later with wax, urethane, or plaster.

RESULTS

The impressions captured illustrate great detail (cleavage-lines, pores, scars, and flesh nuances) without material distortions, air bubbles, or other material defects resulting in poor impression cast.

DISCUSSION

Due to the novel nature of this application method, I have yet to come across any current research attempting to atomized alginate allowing for it to be applied in the propellant aerosol method, which this abstract is built upon. Continued exploration of this method will be developing the rigidity of the mother cast (fiberglass gauze) around the sub cast (alginate) so that the encompassing shape does not become distorted or ruined when removed from the original form and resulting in a discard cast.

CONCLUSION

The goal of this new application of alginate is to increase the impression detail of large surface areas while using only the necessary material needed for capture and to create an alternative method for alginate casting.

CLINICAL APPLICATIONS

The procedural development of alginate as a propellant aerosol would allow for Prosthetists to capture unique anomalies in great detail for development of socket suspension systems, cosmetic prosthetics, and lead to the development of teaching models for Residency students, while conserving materials within their practice.

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No known references at this time to report upon, all information has been acquired through experimentation of alginate materials and previous casting knowledge.

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February 18 - 21, 2015

ASSESSING STEP-BY-STEP VARIABILITY OF GROUND REACTION FORCES AS A MEASURE OF ACCOMMODATION TO PROSTHETIC INTERVENTIONS

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INTRODUCTION

Becoming accustomed to a new prosthesis or orthosis is potentially a lengthy process that may be influenced by a variety of patient- and device-specific factors. This makes it difficult in clinical practice and research to purposefully allocate accommodation times that are neither too short nor too long. As a consequence, patients may be subjected to unnecessarily repetitive optimization sessions – when device fit and alignment changes are conducted in too quick succession – or patients may have to endure prolonged periods using suboptimal devices – when optimization sessions are spaced too far apart. In research studies that involve prosthetic or orthotic interventions, measured effects of such interventions may be influenced by the allowed accommodation time, which may limit the scientific and clinical significance of results and makes it difficult to compare findings of different studies (Neumann, 2009, Geil, 2009).

This pilot study investigated the suitability of kinetics step-by-step variations within the prosthetic leg during walking as an indicator of the level of accommodation to prosthetic interventions.

METHOD

Subjects: Data of 12 subjects that had participated in a prior unrelated study (Fiedler, et. al, 2015) was re-analyzed to investigate the current hypothesis. All subjects used trans-tibial prostheses and were able to walk unaided for several minutes.

Procedure and Apparatus: Prosthesis ground reaction forces of gait were measured continuously over a 20-step sample by means of a load cell (ipecs, RTC Electronics, Dexter, MI) that was temporarily installed into subjects' existing prostheses. The plantarflexion angle of the prosthetic ankle joint was changed by 12 to 18 degrees, depending on the available range of adjustment, between walking trials.

Data Analysis: Data from the first 10 steps after such an alignment change was analyzed by comparing differences in horizontal peak forces between consecutive steps. The found differences were plotted against the step count to visualize the progression over time. An exponential function was fitted through the data points using a best-fit algorithm (Excel, Microsoft, Redmond, WA)

RESULTS

Analysis of a multitude of variables yielded R-squared values between zero and 0.58. Two representative data sets are provided to illustrate the curve trajectories (Figures 1 and 2).

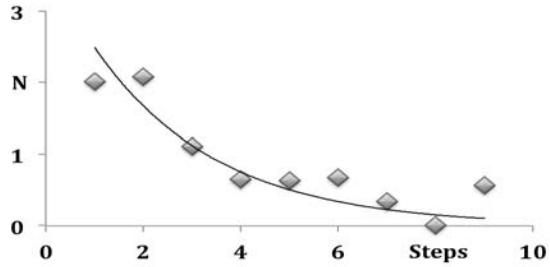

Figure 1: Step-by-step differences in peak medial ground reaction force during the first steps with a newly adjusted prosthetic foot. R^2 here is 0.44.

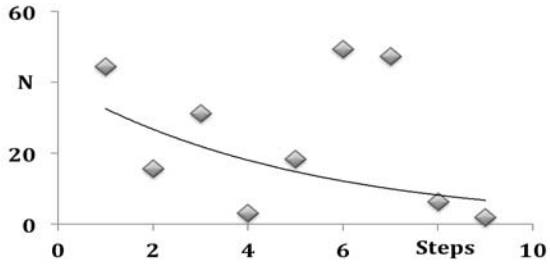

Figure 2: Step-by-step differences in peak medial ground reaction force during the first steps with a newly adjusted prosthetic foot in a different subject. R^2 = 0.19.

DISCUSSION

Our findings could not support the hypothesis that accommodation to prosthesis alignment interventions follows an exponential trajectory. Instead, the data showed a mostly random variance in step-variability across the first steps with a newly adjusted prosthesis, but also across the sample population. It may be concluded that accommodation to prosthetic interventions does not follow a general pattern, or that the here selected variable of ground reaction force differences between steps is not a suitable indicator of the level of accommodation.

CLINICAL APPLICATIONS

Our results support the notion that prosthetic fittings need to account for individual differences between patients that cannot be sufficiently described by general algorithms. Providing the proper amount of accommodation time after changing prosthetic alignments remains a domain of the involved clinician's professional judgement.

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Fluctuations of Plaster Models

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INTRODUCTION

The use of plaster of paris by certified Prosthetists and Orthotists is common practice in their fields. Although this material can be found in nearly every O&P clinic in the country, little is understood about its chemical makeup and behaviour. The chemical makeup of plaster is $2CaSO_4+1/2H_2O$. When plaster is mixed with water it becomes fully hydrated taking its natural form known as gypsum ($2CaSO_4 \cdot 2H_2O$) (Weiser,1932).

The Second World War lead to many advancements in the field of orthotics and prosthetics through focus on material research. When veterans returned with missing limbs, the U.S government and clinicians were both motivated to find materials that would better suit young able-bodied amputees (Lusardi, 2007). Finally after much government funded research we progressed to present day materials. The use of polyethylene, polypropylene, and acrylic carbon-fiber sockets came into the field, becoming the standard of the industry today. With all this advancement in polymer science very little attention was given to the behaviour of plaster of paris.

As is known by most practitioners plaster models dry out overtime and are easily hydrated again by exposing the model to water. However, no one has chronologically measured whether or not there is physical size change in plaster models from its initial manifestation to up to two weeks after the pour.

METHOD

A silicone model of a transtibial amputee will be employed as the original casted limb. A silicone limb was chosen over a human subject for casting as it will remain consistent in size and is not variable due to diet or other morbidities. The transtibial model will be scanned with the Vorum spectra scanner. This scan will be used as the base line to compare the changes in the positive model overtime.

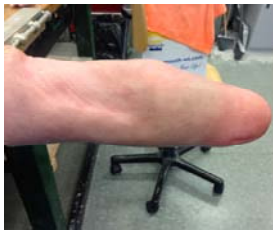

Figure 1. Original silicone Transtibial model ready for 3D scanning.

The positive plaster model will be scanned immediately after it is poured and then it will be stored at room temperature for the two weeks in the absence of direct water contact. After two weeks the model will be scanned again to quantify any differences in size between the chronological scans. Once the scan is completed the model will be submerged in water for several hours and scanned again to see if the common practice of "soaking the model" changes the shape of the plaster.

Figure 2. 3D Vorum Spectra Scanner.

RESULTS

By quantifying the change in plaster models overtime we may better understand some of the variables that lead to ill-fitting orthotic or prosthetic devices. The constant hydration and dehydration of models may skew the shape of the original cast unannounced to the practicing clinician making the task at hand much more difficult.

DISCUSSION

Certified Prosthetists and Orthotists are often challenged when fitting an edematous and/or dysvascualr limb. The fluctuations in limb size depends on diet, lifestyle, and other morbidities. The fluctuations in limb size are due to the inability to regularly excrete water. Since limb size is variable from day to day, fitting prosthetic or orthotic devices with accurate anatomical contour is difficult as the patient is inconsistent in size.

If the positive models are also changing size it would compound the difficulty to fit patients accurately.

CLINICAL APPLICATIONS

The data gathered through this study can be an effective tool for clinicians to refer to. No one really understands to what extant plaster models fluctuate over time. If a clinician modifies a model but a test socket is not pulled until days later it is possible that an undesired fit maybe due to the change in the model and not the patient.

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SUBJECTIVE AND OBJECTIVE EFFECTS OF THE MAL-ALIGNED PROSTHESIS ON THE GAIT OF AN AMPUTEE

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INTRODUCTION

The importance of a well aligned prosthesis is documented. The effects of socket alignment perturbations, specifically in the cardinal planes, have been evaluated in recent years. In 2012, Boone et al studied the patient's ability to communicate mal-alignments to the prosthetist. Hobson et al, found that patients required only a few steps to determine if a mal-alignment was present. The ability to assess mal-alignments was found to be most sensitive in the coronal plane. This study will observe how changes to the alignment of a prosthesis effects the forces and moments at the distal end of the patients socket, the subject's gait, and the subject's comfort in the prosthesis.

METHOD

This is a single subject study of a male unilateral transtibial amputee. He has been in his current prosthesis for greater than 3 months and has fully acclimated to the system. He is able to walk on level ground without the use of an assistive device and has been assessed as a K3 level ambulator. The subject's componentry distal to the socket will be replaced with componentry that allows for adjustability and the addition of an iPecs unit. The patient's test foot will match the patient's current foot. An iPecs unit (Collage Park®) will be used to quantify the forces and moments within the prosthesis. This componentry will initially be optimally aligned by the prosthetist and recorded as base line data; all adjustments will be evaluated relative to this alignment. A prosthetic comfort survey will be administered at the beginning of the session to serve as a control for comparison with the altered alignments. The subject will walk on a treadmill at a self-selected speed for 1 minute to acclimate to the alignment prior to recording data. After the acclimation period, video recordings will begin both in the sagittal and coronal views. Video recording will be captured for at least 30 seconds; then, the subject will be asked to complete a Socket Comfort Score for that particular alignment. One alignment adjustment will be made and the process will be repeated. The table below shows the various alignment adjustments that will be used in this study.

Table of Mal-alignment Combinations

	Evert / Invert	Medial / Lateral	Length
1	0	0	0
2	0	0	-
3	0	-	0
4	0	-	-
5	-	0	0
6	-	0	-
9	+	0	0
10	+	0	-
11	+	-	0
12	+	-	-
13	0	+	0
14	0	+	-
15	-	+	0
16	-	+	-
19	0	0	+
20	0	-	+
21	-	0	+
23	+	0	+
24	+	-	+
25	0	+	+
26	-	+	+

RESULTS

A subject has been selected for the study, componentry has been purchased, and the data collection is scheduled to begin in October with the statistical analysis completed by November.

DISCUSSION

Pending Results

CONCLUSION

Pending Results

CLINICAL APPLICATIONS

The videos collected during the mal-alignment study will be used to develop a simulation program to train students on dynamic alignment. In this program a random video will be presented to the student and they will have the option of changing the angulation, translation, or length to improve the patient's alignment. Once the student selects the adjustment, the corresponding video will be presented to the student. This interactive video library will increase the time that students have to practice dynamic alignment while reducing patient time and any resulting risk. Long term research goals will include the expansion of the video data base to include sagittal and transverse perturbations and possibly extend to transfemoral and orthotic alignment.

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INTREGRATING UNIVERSAL DESIGN FOR LEARNING (UDL) PRINCIPLES INTO THE O&P CURRICULUM

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BACKGROUND

As of January 2013, the field of Orthotics and Prosthetics (O&P) requires a Master's degree in O&P as "the minimum educational standard to become a certified practitioner."[1] Since then, the curriculum guide has been rewritten, with an "enhanced focus on outcome-based education."[1] Outcome-based education is defined as "an approach to education in which decisions about the curriculum are driven by the exit learning outcomes that the students should display at the end of the course."[2] The National Commission on Orthotic and Prosthetic Education (NCOPE) provides each accredited university or college with a standardized list of exit learning outcomes that each student must be able to display prior to receiving his or her master's degree in O&P. The NCOPE standards do not specify educational strategies and teaching methods. This not only allows for innovation in teaching, but actually encourages it.[2] The goal of this project is to describe a specific teaching method known as Universal Design for Learning (UDL), consider its applicability in the O&P curriculum, and examine how it might benefit O&P students.

INTRODUCTION

UDL is "a set of principles for curriculum development that gives all individuals equal opportunities to learn."[3] UDL principles leverage three primary brain network groups: recognition networks, strategic networks, and affective networks. Recognition networks pertain to the "what" of learning. Strategic networks pertain to the "how" of learning. And lastly, affective networks pertain to the "why" of learning.[3] UDL states an individual can learn by leveraging a single technique within a single network, however when given the option to choose multiple techniques within each network, he will learn more quickly retain more longer.

The UDL framework embraces three principles. The first principle stresses multiple means of representation. The second principle stresses multiple means of action and expression. The third UDL principle stresses multiple means of engagement.[6]

CLINICAL APPLICATION

Applying UDL principles to O&P education can significantly improve exit learning outcomes for a wider range of learners.[5] For example, gait analysis is traditionally taught through text books. Media technology has improved exponentially within the last decade. As an additional teaching technique, by having students create their own video analyses of gait teachers offer all students an opportunity to engage with the material in a different way and deepen their recognition and understanding of gait anomalies.

Furthermore, by adapting O&P education programs to teach as well as use UDL principles, students (who are on the way to becoming clinicians) can later integrate the principles in practice to communicate with their patients more effectively.

This poster will address these two points and include additional examples. It will also include an outline of possible options for O&P teachers to leverage for their own classes.

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Evaluation of Additive Manufacturing (3D Printing) in the Field of Prosthetics and Orthotics

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INTRODUCTION

The aim of this research is to provide substantial background information which the United States Association of International Development (USAID) can use to communicate the effectiveness of Additive Manufacturing (AM) colloquially known as 3D Printing in the field of Prosthetics and Orthotics (P&O). AM technology is predicted to become a $6.1 million industry by 2017 (Wohlers, 2013). The recent developments in technology and materials have led to excitement about products within O&P such as printed prosthetic sockets (Herbert, 2005). We investigated P&O practitioner knowledge about AM to determine attitudes towards AM and its usefulness in clinical practice.

METHOD

Subjects: Subscribers to an electronic mailing list, the OandP.com ListServe, were recruited as participants.

Procedure and Apparatus: This research used a ten question survey administered by an online data collection platform (Google Forms). The first part of the survey contained questions designed to estimate responders' knowledge level, using multiple choice questions with several incorrect and only one correct answer choice (Table 1). The second part of the questionnaire assessed opinions and attitudes toward AM (Table 2).

Table 1: Sample Multiple Choice question with answer choices

In your opinion, which of the following is NOT a 3D Printing manufacturing process?	
A)	FDM – Fused Deposition Modeling
B)	SL – Stereolitography
C)	DLM – Digital Light Modelling
D)	CLM – Calorimeter Laser Modeling
E)	Not sure

Table 2: Sample Opinion question with answer choices

3D Printing is a beneficial tool in the fabrication of prostheses and orthoses									
1- Completely agree	2	3	4	5	6	7	8	9	10- Completely disagree

Data Analysis: Preliminary data was analyzed and answer partitioning was performed to provide a scoring of the first four survey questions. Later analysis will evaluate remaining answers.

The methodology obtained IRB exemption status.

RESULTS

The research survey yielded 68 responses. Responses to the first four questions allowed a coarse rating of participant's knowledge about AM. The mean score was 46% with a standard deviation of 35 in a non-normal distribution (Figure 1).

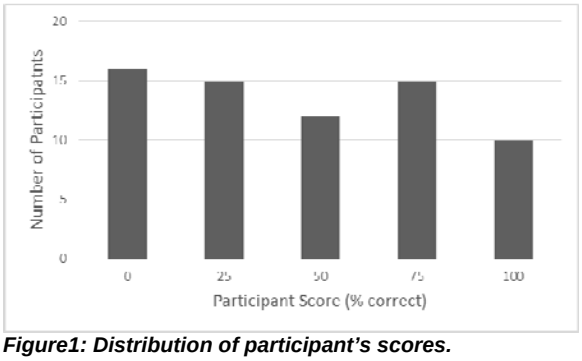

Figure1: Distribution of participant's scores.

Preliminary review of the opinion questions indicates that AM technology would generally be accepted in clinical practice. 51% of respondents disagree with the statement that AM would replace practitioners within the next 20 years. Similarly, 23% agree with the statement that AM is a beneficial tool in the fabrication of prosthetics and orthotics. Finally 27.9% stated that they would spend the time, money, and energy necessary to be trained to use a 3D Printer.

DISCUSSION

Our research found a more positive attitude on AM among P&O clinicians than anecdotal evidence may suggest. The results demonstrate a range in the level of understanding of the technology. Future use of this information can provide a baseline to monitor the attitude towards AM as it becomes a more intensely debated technology in the field of O&P. The acceptance of AM technology within this sample is higher than expected. However, specific technical knowledge is somewhat limited.

CLINICAL APPLICATIONS

The use of AM in the field of O&P holds promises of easier customization to patients at lower costs (Herbert, 2005). Currently the technology is used in a wide variety of applications (Gerbhardt, 2011). A background of the technology and opinions within the field of O&P will help guide decisions surrounding adoption in clinical practice or in USAID endeavours.

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Upper & Lower Knee Ab/Adduction Moment Sensing

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INTRODUCTION

Knee Osteoarthritis (KOA) is estimated to affect over 13% of the US population older than 45 years of age (Turciewicz, 2014). Indeed, the lifetime risk of developing symptomatic KOA for Americans has been estimated to be 44.7% (Murphy, 2008). Knee abduction/adduction moment (KAM) is recognized as a primary marker of KOA progression. A 1% increase in peak external KAM has been linked to a greater than 6-fold increase in the risk of KOA progression (Miyazaki, 2002).

Due to high costs, and limited measurement granularity, established KAM measurement techniques are an impractical means for tracking KOA progression. Measurement of KAM is currently limited to gait laboratories, which utilize motion capture systems to determine knee moments (van den Noort, 2013; Cappozzo, 1995). KOA often takes decades to develop. Identifying statistically significant changes in KAM on a year over year (or more frequent) basis therefore requires a higher degree of granularity than current techniques offer. Other attempts at measuring KAM during free ambulation have neither achieved complete independence from lab measurements, nor generated significantly greater granularity (van den Noort, 2012; van den Noort, 2013).

In this work, a novel means of measuring KAM during free ambulation is presented, offering determination of KAM with high measurement accuracy and measurement granularity. We have developed an orthotic leg brace containing pressure sensors located on the inner and outer shank and thigh regions that measure side forces. From these side forces, we have measured the forces generated by the knee that are balanced by the legbrace.

METHOD

Subjects: We performed a preliminary test on a 75-year old male **not** being treated for KOA with the legbrace set to its passive mode of operation. The subject walked on a treadmill at 2.2 miles per hour with an average step length 23.434 inches and average step period of 0.6052 seconds. Legbrace side force sensors were sampled at 4,608 samples per second. Sensor measures were created by adding 12 successive sensor samples and recording them on the legbrace's non-volatile memory. Additional Gait measures logged included: knee angle, shank tilt angle, shank lean angle, heel pressure, ball-of-foot pressure, foot angle and torso support force supplied by the legbrace. *Apparatus*: Sensor data were stored in Gait measurements of the subject were also taken using the lab-based motion capture system.

Procedures: The subject walked on a treadmill while data were collected by the brace and laboratory motion capture systems. After testing, data were processed using Wolfram's Mathematica. Motion capture data were analysed using commercially available software.

RESULTS

The novel approach used in this work generated KAM measurements that were lower than those generated by traditional techniques. Plots of data collected by laboratory and PUUMA KAM measurement systems are given in Figures 1 and 2.

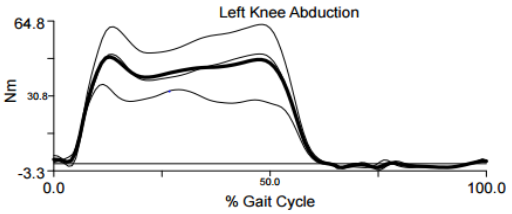
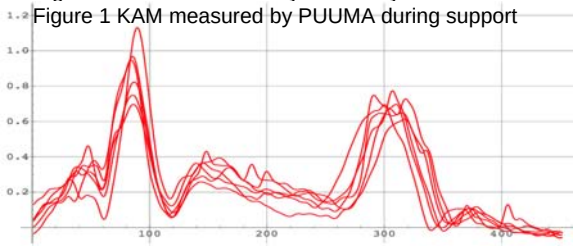


Figure 1: KAM measured by laboratory.

Figure 1 KAM measured by PUUMA during support



DISCUSSION

Our novel method for measuring KAM measures all discernable side forces exerted by the legbrace. These side forces began prior to heelstrike and peaked immediately following heelstrike and again prior to toeoff. Sensor calibration has not been completed preventing analysis of relative pressures between the brace and traditional methods.

CONCLUSION

The legbrace KAM measurements showed significant peaks not present in traditional KAM measurements. Further testing will be required to ascertain if these peaks are anomalous; peculiar to the brace/test; or are simply not detected by traditional methods. The potential for measuring KAM accurately and with the desired level of granularity is promising but unproven.

CLINICAL APPLICATIONS

The high accuracy and fine granularity side force measurements our method provides has the potential of creating a novel means of tracking/managing KOA.

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Van den Noort et al. Journal of Biomechanics 46, 43-49, 2013.

DEVELOPMENT OF LOW COST 3D PRINTED TRANSITIONAL PROSTHESES

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INTRODUCTION

There are increasing numbers of children with traumatic and congenital amputations or reductions. Children's prosthetic needs are complex due to their small size, constant growth, and psychosocial development (Krebs et al., 1991 and Zuniga et al. 2015). Families' financial resources play a crucial role in the prescription of prosthetics for their children, especially when private insurance and public funding are insufficient. Electric-powered (i.e., myoelectric) and body-powered (i.e., mechanical) devices have been developed to accommodate children's needs, but the cost of maintenance and replacement represent an obstacle for many families. Due to the complexity and high cost of these prostheses, they are not accessible to children from low income, uninsured families, or to children from developing countries (Krebs et al., 1991 and Zuniga et al. 2015). Advancements in computer-aided design (CAD) programs and additive manufacturing offer the possibility of designing and printing prostheses at a very low cost (Zuniga et al. 2015). The purpose of the present investigation was to demonstrate the manufacturing methodology of 3D printed transitional prostheses, examine improvement in perceived changes in quality of life, daily usage, and activities performed with these types of devices.

METHOD

Nine children (two girls and seven boys, 3 to 16 years of age) with upper-limb reductions (one traumatic and eight congenital) were fitted with our 3D printed transitional prostheses and were asked to complete a survey. Inclusion criteria included boys and girls from 3 to 17 years of age with unilateral upper-limb reductions. Exclusion criteria included upper extremity injury within the past month and any medical conditions that would be contraindicated with the use of our 3D printed prostheses prototypes, such as skin abrasions and musculoskeletal injuries. The study was approved by the Creighton University Institutional Review Board and all the subjects completed a medical history questionnaire. All parents and children were informed about the study and parents signed a parental permission. For children 6 to 17, an assent was explained by the principal investigator and signed by the children and their parents. The survey was developed to estimate the impact of our prosthetic device including items related to quality of life, daily usage, and type of activities performed

RESULTS

After approximately 1 to 3 months of using our 3D printed prostheses 11 children and their parents reported some increases in quality of life (4 indicated that was significant and 7 indicated a small increase), while 1 indicated no change. Nine children reported using the device 1 to 2 hours a day, 3 reported using it longer than 2 hours and 1 reported using it only when needed. Furthermore, children reported using our 3D printed prostheses for activities at home (9), just for fun (10), to play (6), for school activities (4), and to perform sports (2). Four children reported malfunctioning and/or breaking of the 3D printed prosthetic device.

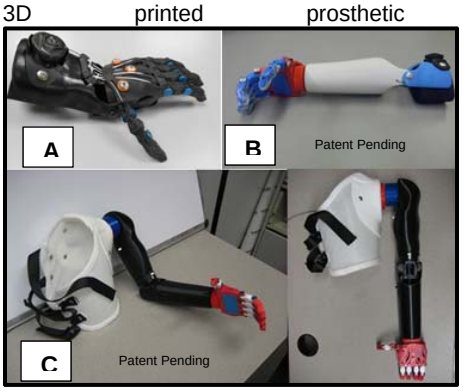

Figure 1. Shows some of the 3D printed transitional prostheses prototypes developed by our research team. A: Hand prosthesis (Cyborg Beast); B: Below Elbow Device; C: Prosthetic Shoulder.

DISCUSSION

The main finding of our survey was that our 3D printed transitional prostheses have a great potential in positively impact quality of life, daily usage, and can be incorporated in several activities at home and in school. However, 36% of our research participants reported durability issues and/or malfunctioning of these devices. There is a need to develop medical grade 3D printed prosthetic devices to solve the durability constrains.

CONCLUSION

Although, durability and environment are factors to consider when using 3D printed prostheses, the practicality and cost effectiveness represents a promising new option for clinicians and their patients. 3D printing technology for the development of prosthetic devices is at a very early stage. The supervision of a certified prosthetist is crucial for the proper development and use of 3D printed prostheses.

CLINICAL APPLICATIONS

3D printed transitional prostheses have a great potential in positively impact quality of life, daily usage, and can be incorporated in several activities at home and in school. The supervision of a certified prosthetist is crucial for the proper development and use of 3D printed prostheses.

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INCREASES IN ROM AND CIRCUMFERENCE OF THE FOREARM AFTER 6 MONTHS OF USING A 3D PRINTED TRANSITIONAL HAND PROSTHESIS

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INTRODUCTION

Children's prosthetic needs are complex due to their small size, constant growth, and psychosocial development (Krebs et al., 1991 and Zuniga et al. 2015). Independent of the type of limb deficiency (congenital or traumatic) muscle atrophy, loss of mobility, and asymmetry are typical characteristic of the affected limb (Krebs et al., 1991 and Zuniga et al. 2015). Most upper-limb prostheses for children include a terminal device, with the objective to replace the missing hand or fingers. Electric-powered units (i.e., myoelectric) and mechanical devices (i.e., body-powered) have been improved to accommodate children's needs, but the cost of maintenance and replacement represent an obstacle for many families (Krebs et al., 1991 and Zuniga et al. 2015). The development and use of low-cost transitional prosthetic devices to increase ROM, strength, and other relevant clinical variables would have a significant clinical impact in children with upper-limb differences. Thus, the purpose of the study was to identify anthropometric, active range of motion, and strength changes after 6 months of using a wrist driven 3D-printed transitional prosthetic hand for children with upper limb differences.

METHOD

Subjects: Five children (two girls and three boys, 3 to 10 years of age) with absent digits (one traumatic and four congenital) participated in this study and were fitted with a low-cost 3D-printed prosthetic hand.

Apparatus: Anthropometric, active range of motion, and strength measurements were assessed before and after 6 month of using a low-cost 3D printed prosthetic hand.

Procedures: Six variables from the affected and non-affected hand including circumferences, skin folds, and active ROM for flexion, extension, radial deviation, and ulnar deviation were measured on each research participant by a trained occupational therapist.

Data Analysis: Seven separate two-way repeated measures ANOVAs [2 x 2; hand (affected versus non-affected) x Time (before and after)] were performed to analyze the data. A p-value of $\leqslant 0.05$ was considered statistically significant for all comparisons.

RESULTS

There were significant hand × time interactions for the forearm circumference [$F(1,4) = 16.90$; $p = 0.02$], active ROM flexion (Fig. 1) [$F(1,4) = 12.70$; $p = 0.02$,], and active ROM extension values [$F(1,4) = 8.80$; $p = 0.04$]. There were no significant hand x time interaction, however, for wrist flexion strength [$F(1,4) = 1.48$; $p = 0.29$], wrist extension strength [$F(1,4) = 0.05$; $p = 0.84$], active ROM UD [$F(1,4) = 0.65$; $p = 0.5$], active ROM RD [$F(1,4) = 1.77$; $p = 0.25$], and forearm skinfold values [$F(1,4) = 4.24$; $p = 0.11$].

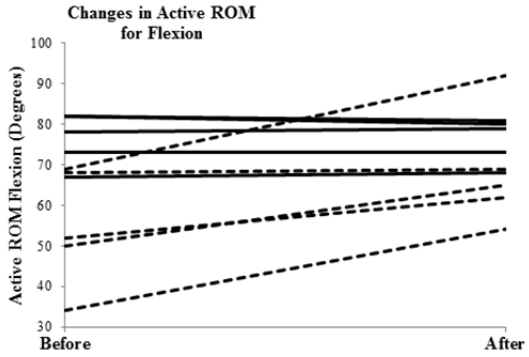

Figure 1. shows individual changes for active range of motion (ROM) for wrist flexion before and after a 6 month period of using the low-cost 3D printed transitional prosthetic device.

DISCUSSION

The main finding of the present investigation was that the usage of a low-cost 3D printed transitional prosthetic hand significantly increased forearm circumference (Before=16.70±1.86 cm and After=17.80±1.48 cm), wrist active ROM flexion (Before=54.60±14.48° and After=68.40±14.29°), and active ROM extension (Before=40.40±37.75° and After=47.00±36.42° cm) on a small sample of children with upper-limb differences. Thus, the Cyborg Beast transitional prosthetic hand represents low-cost prosthetic solution for those in need of a transitional device to increase ROM.

CONCLUSION

Although, durability and environment are factors to consider when using 3D printed prostheses, the practicality and cost effectiveness represents a promising new option for clinicians and their patients.

CLINICAL APPLICATIONS

Six month of using this 3D printed transitional prosthesis increased forearm circumference, wrist active ROM flexion, and active ROM extension in children with upper-limb differences.

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OPTIMIZING PLASTER MIXTURES BASED ON CURING TEMPERATURE, MATERIAL RATIOS, AND FINANCIAL COST

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INTRODUCTION

Plaster is a common material used in the production of prosthetics and orthotics. Clinicians take a negative cast of a patient's limb to create a positive model out of plaster for modifications and production. Traditionally, the mixture ratio of plaster to water has been subjectively determined by the practitioner. The subjective nature of this approach could result in wasted material that increases production costs. Reimbursement from Medicare and third party payers for P&O services continues to decrease, making a reduction in material costs beneficial to practice management. However, by reducing the amount of plaster and increasing the volume of water, curing temperature is expected to decrease, therefore increasing curing time, which could negatively affect production costs. The purpose of this study was to define the optimal ratio of plaster to water that maximizes curing temperature and minimizes the financial cost.

METHOD

Five mixture ratios were used, starting with the standard mixing ratio given by United States Gypsum Corporation (100 parts plaster: 70 parts water) and including ratios with more plaster (105:65 & 110:60), as well as ratios with more water (95:75 & 90:80). Five PVC pipes (3"x10") were used to create cylindrical plaster molds. The plaster was poured and the surface temperature of each model was taken using an infrared thermometer at five-minute increments for one hour. The cost of the plaster sample was found by taking the dry weight of plaster and dividing it by the cost of the plaster per gram. Plaster was purchased at $11.90 per fifty-pound bag. Optimal mixture was calculated by first normalizing cure temperature and cost to the control mixture (100:70). Increasing cure temperature should correlate to a stronger mixture and is considered a positive outcome so the formula used was (cure temperature of ratio(n) / cure temperature of 100:70 ratio). Decreasing cost is considered a positive outcome so the formula used was (cost of sample ratio(n) / cost of 100:70 ratio). Linear interpolation lines were then drawn through these data points. The optimal plaster ratio would then be the intersection of these two lines.

RESULTS

Peak curing temperature and cost both increased with increasing the relative amount of plaster in the mixture. Peak cure temperature was 88.1°, 86.5°, 90.5°, 80.3°, and 80.9° and cost per sample were $0.57, $0.54, $0.52, $0.49, $0.46 for 110:60, 105:65, 100:70, 95:75, and 90:80 respectively. The optimal plaster ratio was very close to the amount recommended by the United States Gypsum Corporation (100:70) (Figure 1).

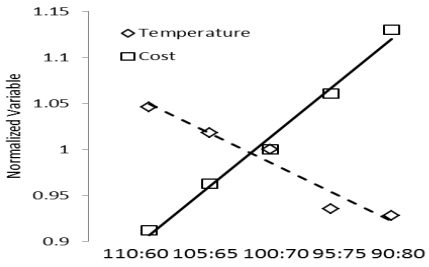

Figure 1 - Optimal mixture that balances cure temperature and cost was close to the recommended amount of 100:70 (intersection of the two lines).

DISCUSSION

These results show that as the amount of plaster increases, temperature will also increase, therefore decreasing curing time. This is beneficial for increased productivity because the positive model can be modified earlier. However, the current optimization method places an equal weighting on temperature and cost. This may not be the best assumption because the time saved by curing at a higher temperature and the strength associated with higher temperatures may result in additional cost savings due to increased productivity (decreased labor costs) and lower probability of model damage during fabrication (decreased labor and plastic costs). These indirect cost savings may exceed the additional direct costs of using more plaster and underscore the need to develop a better optimization model.

CONCLUSION

In conclusion, this data currently suggest the optimal plaster ratio is close to the manufacturer recommendation of 100:70 but more research is necessary to account for how these ratios affect strength and productivity in a P&O setting. This research is a necessary first step to improve practice management in an ever-changing reimbursement environment.

CLINICAL APPLICATIONS

Plaster is a common material used in P&O clinics and optimization of manufacturing using plaster will help reduce costs associated with providing clinical care.

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Effect of transtibial prosthetic alignment change related to asymmetry gait pattern and fundamental motion measurement

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INTRODUCTION

To date there are no studies having assessed the relative outcomes of the final dynamic prosthetic alignment and the recommended static prosthetic alignment, and how these are related. Does the recommended static alignment influence and confirm more symmetrical gait during dynamic analysis in terms of kinematic and kinetic measurement? This project aimed to evaluate the clinical results of the final total static weight line of transtibial amputees using a 3D motion analysis system by measuring the differences between the final total static weight line and the recommended static alignment, and then comparing the effect of total static weight line changed with asymmetrical individual gait pattern in terms of kinematic and kinetic analysis.

METHOD

Subjects: Ten unilateral transtibial amputees with at least one year experience of endoskeletal transtibial prosthesis user participated in this study. All participants routinely used the same prosthetic type endoskeletal prosthesis with patellar tendon bearing socket and multi-axial prosthetic foot.

Procedures: The Vicon® motion capture System was used to collect the static and dynamic data, and the differences in gait parameters values between two groups of participants' total static weight line were analysed collectively.

Data Analysis: Six participants were included in anterior weight line group which their total static weight line were represented by GRF passing anteriorly through the knee joint while four remaining participants were defined in posterior weight line group that their total static weight line were signified GRF passing posteriorly. Symmetrical kinematic/kinetic data within subject between both limbs was compared by a general linear model for repeated measures, then those values were combined and analysed to provide mean results of all ten participants and compared the significant difference among participants in each group.

RESULTS

The sound side exerted greater effort during the gait cycle as observed from most of the kinematic and kinetic curves that represented high magnitude values when compared to the prosthetic side. The kinematic and kinetic variables showed that the joint relative angles, joint forces, and joint powers were of more symmetrical in the posterior weight line groups. However, the anterior weight line group presented more symmetrical in terms of time and distance parameters. The kinematic and kinetic data represented asymmetrical gait frequently in mid-stance and terminal stance phases.

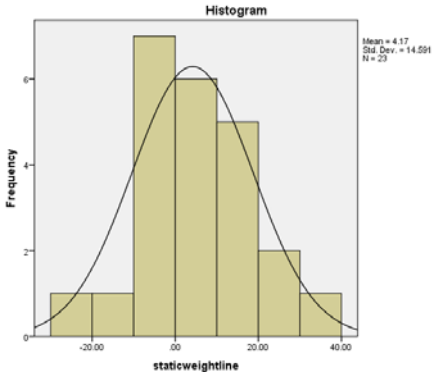

Figure1. Frequency distribution of the AP total static weight lines displacement of 10 unilateral transtibial participants

DISCUSSION

Firstly, the sound side exerts more effort during the gait cycle so asymmetrical gait may be the means by which the sound side tries to protect the residual limb. Secondly, the joint relative angles, joint forces, and joint powers are of more symmetrical parameters in the posterior weight line group. However, the anterior weight line group presents more symmetrical in term of time and distance. Lastly, the joint angles and the joint forces represent asymmetrical gait frequently in mid-stance and terminal stance phases as a consequence of the less stability of the prosthetic side during the single limb support phase.

CONCLUSION

Asymmetrical gait pattern in terms of kinematic and kinetic parameters were not influenced by how severely the final prosthetic alignment differed from the recommended static alignment in this present study results.

CLINICAL APPLICATIONS

The process of evaluating and learning 3D measurement systems could help researchers and clinicians to develop acknowledgement of the prosthetic alignment system and transtibial amputee gait clinical analysis.

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3D PRINTED LOW-COST UPPER EXTREMITY VISUAL AND TACTILE FEEDBACK SYSTEM

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INTRODUCTION

Upper extremity prostheses (UEP) can never fully replace the function, sensation and expressiveness of a human hand (Dapka, 1997). This is supported by commonly cited reasons for abandonment of use of UEPs, which include user perception of comfort and function (Biddiss, 2007). The ability to "feel" objects (force feedback) provides better function through enhanced control. New technologies attempt to provide this (Catalano, 2014) at high cost or requiring invasive procedures. Lower cost devices have also been attempted (Pylatiuk, 2006).

One of the keys to learning how to effectively use a newly fit prosthesis is to understand the different localizations of sensations (the somatosensory map). This is even more important when force feedback is sought. Cutaneous feedback from the grasping or contact surface is influenced by muscles forces controlling the hand and arm (Jones, 2006). Redirecting these grip forces in prostheses can help create alternate force sensation. The contact cue (temporal aspect) is vital to effective UEP use since our nervous system relies on near-instantaneous feedback. Neurons are influenced by joint position which is reciprocally influenced by both visual and proprioceptive cues (Graziano 1999).

The goal of this project was to design a low cost system that can be retrofitted to existing EUPs and provide grip force feedback at a proximal location on the user's arm, while avoiding complexities inherent in existing systems.

METHOD

When even minimal grip force is applied to the fingertips of the prosthesis, it is translated into visual feedback via an LED on the fingertips as a cue to the user. As grip force increases, it is reflected as grip strength via a force being applied to a mechanism on the residual upper arm at an intact, sensate area.

RESULTS

Because this device is in the alpha prototype stage of development, no results regarding reliability are available. *NOTE: Results will be available at the time the poster is presented, as beta versions are being developed.*

This device is the result of new developments following work of a previous terminal force feedback system prototype presented at last year's academy meeting. This prototype is currently being tested for both acute and long-term use in multiple forms in order to be applicable to both amputees and sound hand users.

DISCUSSION

The ability to wear and properly use this device due to its low cost and simplicity provides the potential to benefit a broad spectrum of UEP users. Current areas of exploration include an attachable design to fit over existing myoelectric and body powered prostheses with sagittal plane grip force with thumb adduction and finger flexion.

CLINICAL APPLICATIONS

This device was designed to improve patient compliance by allowing feedback from the prosthetic limb to produce sensations that creatively mimic a functional, sound hand. Both the patient and the practitioner can benefit from its use, as it can help provide a mutual understanding of the patient's needs and the capabilities of the prosthesis.

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MOBILE APPLICATION FOR TRACKING LOWER LIMB AMPUTEE FITNESS

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INTRODUCTION

The number of amputees living in the United States is projected to double to more than 3 million by 2050. As this population grows, healthcare professionals, including prosthetists, must consider the unique physiology of amputee patients when formulating treatment plans, setting goals, and creating wellness regimens. Due to their altered anatomy, amputees must consider weight control, muscle strength, joint health, and cardiovascular fitness as crucial parts of their overall wellness (Kahle & Highsmith, 2008).

Studies have demonstrated that energy expenditure during ambulation is significantly higher for amputees compared with non-amputee subjects (Schmalz, Blumentritt, and Jarasch, 2002, Waters & Mulroy, 1999). This is an important consideration for amputees as they work to safely maintain a healthy weight, particularly in light of the fact that amputees are more likely to have concurrent cardiovascular disease (Frugoli, Guion, Joyner, McMillan, 2000). In order to create fitness regimens that are safe for amputees with cardiovascular disease and other comorbidities, knowledge of caloric output is critical.

The amputee population is largely overlooked by the fitness industry. Despite the difference in caloric needs, there are currently no tools on the market for calculating and recording energy expenditure for amputees. There is a need for a user-friendly, accurate, and accessible tool for amputees to track their physical activities and caloric balance. The current project is to design a mobile application ("app" for cellular phones, tablets, etc) which would provide estimated caloric expenditure for transtibial and transfemoral amputees while walking or running.

METHOD

Subjects: No human subjects will be used in the study.

Apparatus: N/A

Procedures: The project will be based on results from an extensive literature review examining energy expenditure of transtibial and transfemoral amputees. The data from existing literature will be used to generate formulas for estimating caloric output of amputees while walking and running. These formulas will create the framework for a future mobile app to track amputee fitness.

Data Analysis: The results from existing studies will be assessed in order to establish average values. No new data will be collected or analyzed by the author.

RESULTS

The literature review will result in a collection of detailed formulas for estimating caloric output for lower limb amputees while walking and running. An informal program specification will be created in order to facilitate future development of a mobile app. Once the study is complete, the author will consult with app developers to discuss the feasibility of producing a serviceable app for public distribution.

DISCUSSION

It has been demonstrated that the energy needs of amputees differ from non-amputees, yet fitness tools which specifically cater to amputees do not exist. The proposed app would serve as a valuable resource for amputees pursuing a healthier lifestyle while filling a gap in the current technology. The current project is limited by the availability of experimental data comparing energy expenditure for amputees versus non-amputees. More research is needed in order to further refine the formulas and include more activities in the app. Future studies could also examine the possibility of using data collected by the app as an outcome measure.

CONCLUSION

Amputees would benefit from a fitness app designed to consider their unique energy requirements. Use of such an app would aid individuals seeking to improve or maintain physical fitness while providing prosthetists with quantitative data detailing their patients' progress.

CLINICAL APPLICATIONS

Encouraging physical fitness in an at-risk patient population could have positive consequences across numerous healthcare disciplines. Ultimately, any tool that serves to improve the overall health and fitness of amputee patients is a benefit to prosthetists. Furthermore, the proposed app would allow prosthetists to track rehabilitation progress, record changes in activity level, and provide evidence of patient motivation.

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A method to analysis dynamics properties of trans-femoral prosthesis

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INTRODUCTION

A lower limb prosthesis is designed to replace the functions of the missing lower limb. An understanding of the structure's dynamic properties and the load transfer between the socket of the prosthesis and the residual limb is important to the evaluation of the quality of a prosthesis.

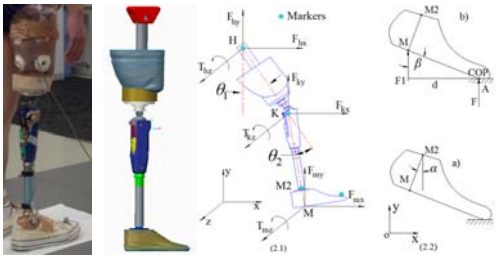
In this study, the authors modeled the residual limb and prosthesis with two links. Each part of the prosthesis was modeled in full size. These results show the forces and moments acting on the hip and knee joints in the dynamic state. This method offers greater flexibility and the calculation requires less time.

METHOD

The subject in this study was a man with a right-side trans-femoral amputation. He was aged 47, 167 cm in height, and weighed 61 kg without his prosthesis. His prosthesis incorporated a UCLA socket, a Nabco prosthesis, and an Ottobock foot.

The kinematic data for the lower-limb and prosthesis, as well as the reaction forces applied to the prosthesis foot while walking were measured using a Mac3D system and a force plate platform. Data was recorded at a sampling rate of 200 Hz while the subject was walking..

Fig.1 shows the actual lower limb with the prosthesis and the 3D model. A 3D model of the residual limb and socket prosthesis were created using MRI data.. The dimensions of the parts of prosthesis were taken from the actual prosthesis.



(a) (b)

Fig. 1. Real and 3D model of lower limb with prosthesis (a) Position of markers and angles on lower limb and foot (b).

The data determined with Creo, including the material density, inertia moment, geometry data, and constraints were exported to Simmechanics (MathWorks). The initial simulation parameters consisted of the angle, angular velocity, and the angular acceleration at the hip and knee joints. The reaction force and moments at the foot were calculated from the measured data.

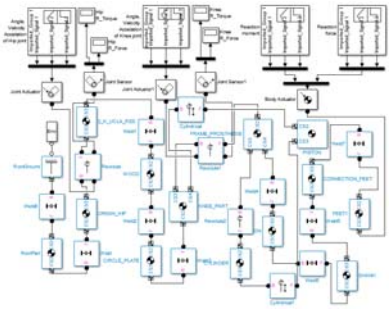


Fig. 2. The block diagram in SimMechanics

RESULTS

The forces and moments at the hip and knee joints as determined using Simmechanics. Fig 3 shown the moment at M point, hip and knee joint.

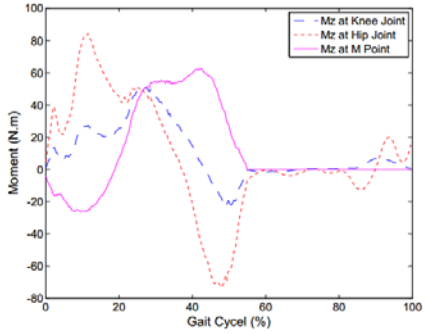


Fig. 3 Moment at point M, hip, and knee joints

DISCUSSION

The graphs of the reaction force at the hip and knee joints are almost the same as the ground reaction force. The direction of the moment at point M and at the hip and knee joints are reversed. The maximum and minimum moment of the hip joint appear in the heel contact and toe off periods, respectively.

CONCLUSION

From these results, we have a flexible method to calculate the forces and moments applied to the hip and knee joints, and the load transfer between the socket and the residual limb.

CLINICAL APPLICATIONS

These results could be used to analyze the socket, and enable the quantitative evaluation and optimization of prosthesis.

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An Analysis of Current Prosthetic and Orthotic Literature Authorship Characteristics, Study Design, and Location

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INTRODUCTION

The field of prosthetics and orthotics (P&O) began focusing on increasing evidence-based practice (EBP) in the 1990's and its importance has since increased due to pressure to improve patient outcomes and to justify component use (Andrysek et al., 2011). However, there is currently a divide between published research and the usefulness of that research to practitioners. Giel (2009) states that even clinically based research, which should be the most clinically applicable, often fails to meet the expectations of clinicians. Giel concluded that the more clinicians perform research, the more that research should be clinically applicable.

This study attempts to quantify the changing rates of P&O practitioners publishing research over the years 2007 to 2015. Visualizing the locations and type of research in a heat map provides insight into the current state of P&O literature. It was hypothesized that as the education standards rise and EBP becomes more important, the percentage of P&O professionals publishing literature should increase.

METHOD

P&O related articles from *JPO-Journal of Prosthetics and Orthotics, Prosthetics and Orthotics International*, *Journal of Rehab Research and Development*, and *Archives of Physical Medicine and Rehab* published from the years 2007 to 2015 were sorted into a database. Journals were selected from the list of the top-cited articles in limb prosthetics as set by Eshraghi et al. (2013). It is assumed that these four journals provide a nearly comprehensive amount of articles based on the percentage of the results of a PubMed search for prosthetic limb and orthotic device articles from the years 2007 to 2015. Data from each article was then sorted into key categories: Title, Journal, Issue, Volume, Publication Year, Sackett's Rule of Evidence as described by Eshraghi et al., Research Design, Country, State (if US), City, P&O Professional as an Author, and as First or Second Author. Categories are based upon Ramstrand and Brodtkorb (2008) and their six year retrospective study of primary authors in *JPO* and *Prosthetics and Orthotics International* from 2000 to 2006.

Data Analysis: Data will be organized into heat maps according to publication location and year as well as bar graphs by year, P&O professional authorship percentages, and by type of study.

RESULTS

Preliminary results from 200 reviewed articles (Figure 1) indicate a trend toward fewer P&O professionals publishing relevant literature in the field.

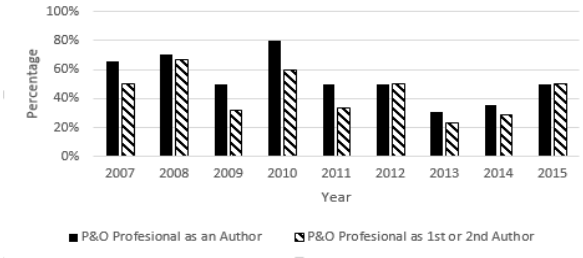

Figure 1. Preliminary results of the percentage of prosthetics and orthotics professionals as authors for research in the field.

DISCUSSION

The preliminary results show a trend toward a decreasing percentage of P&O professionals as authors on published literature which is a direct opposite of the findings of Ramstrand and Braodtkorb (2008) in their analysis from 2000 to 2006 who found a trend toward increasing percentages. This challenges the hypothesis that the percentage of P&O professionals publishing research would increase as education standards and the push for EBP increases. A possible explanation could be a lack of clinician funding or time to preform research or a greater increase in the amount of research produced by people outside of the prosthetics and orthotics field.

CONCLUSION

The preliminary data indicates that the percentage of P&O professionals publishing research is falling. This trend is worrying as it may indicate less clinically relevant data that could be used to justify clinical decisions.

CLINICAL APPLICATIONS

This study will help clinicians easily identify which journals have the highest percentages of P&O professionals as authors. This will help clinicians easily identify journals with potentially relevant research. In addition, it will show trends as to publication location and whether or not P&O professional contribution to EBP has been increasing or decreasing.

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3D Printed Dexterous Prosthetic Foot Control and Structure Design

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INTRODUCTION

This project focuses on the analysis and design of 3D printed lower limb prosthetic structures. Throughout the teams research the discovery that options for materials to build the structure of the prosthetic foot were very limited. The major choices are 3D printed plastics, carbon fiber, titanium, steel and aluminum. The team has also done a large amount of research into 3D printing and has decided to prototype the final design using a 3D printer. The major reason for this is that it allows for a product to be manufactured fast and very easily. The features that have been designed and built are the ball of the foot, structural bars, heel and central ball. This prosthetic foot is load bearing but has not been tested with human subjects. The team has also conducted material strength test of 3D printed Materials. With the use of 3D printers, the team has printed six different configurations of materials.

METHOD

Apparatus: Makerbot 2X, Instron 5882, Tinius Olsen compression/tension tester, SolidWorks Educational Edition

Procedures: Standard samples were produced from ABS, PLA, and PLA-Carbon Fiber composite by Fused Deposition Modeling (FDM), then were drawn by an Instron 5882, and the resulting data was plotted for clarity. A material was chosen to proceed, and a design was created to utilize the properties of that material. A safety factor of 3 was chosen.

Data Analysis: Toughness, Elasticity, and Plasticity were assessed by 0.2%-strain method.

RESULTS

The final structure using the data collected from the materials study was tested to 534 pounds on the hydraulic compression tester. This number comes from the constraint that the average person weighs 178 pounds and with a safety factor of 3.

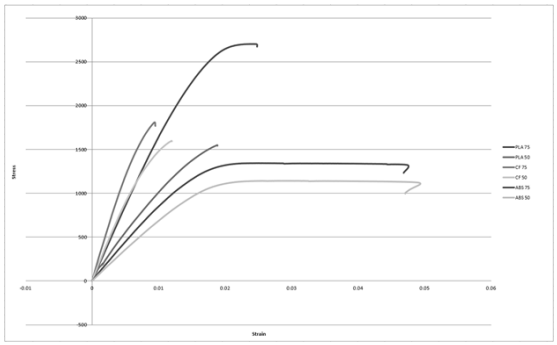

Figure 1: Stress versus strain chart of the six 3D printed configurations that were tested.

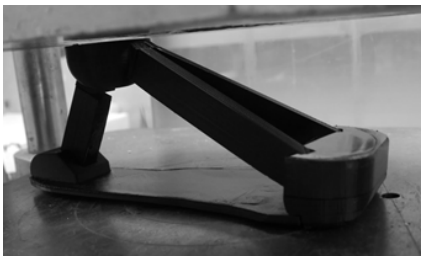

Figure 2: 3D printed model in compression tester

DISCUSSION

Through conducting the materials study the team learned about the material characteristics of FDM thermoplastics. These included carbon fiber impregnated PLA, ABS, and PLA as a standalone material.

CONCLUSION

After testing the three types of materials for overall strength, the standard ABS proved to the most effective for our project. The final structure was able to withstand the safe 534 lbs. of compression with only minor plastic deformation.

CLINICAL APPLICATIONS

This is an ongoing project that will produce a novel prosthetic foot structure which is intended to replace the functions of a natural human foot.

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RETROSPECTIVE CHART REVIEW OF DATA ON BODY AND PROSTHESIS MASS OF PEOPLE WITH TRANS-TIBIAL AMPUTATION

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INTRODUCTION

Following a trans-tibial amputation (TTA) only part of the original limb musculature remains. The amount of musculature lost below the knee could affect the user's control over the trans-tibial prosthesis (TTP). To ensure that the user has a good control over the TTP, an ideal prescription would need to take into account many important factors, one of which is the mass of the TTP. Currently however, there is lack of evidence on optimal mass configurations of TTP to guide clinical practice. One key aspect towards finding optimal mass configurations of TTP is to understand the relationship between the user's body and TTP mass. Knowledge of this relationship may help in standardizing future recommendations for clinical practice. Hence, the purpose of this study is to find the relationship between TTP mass and different body segment masses/lengths.

METHOD

Subjects: Data on 13 individuals with unilateral TTA. Mean height and body mass of 1.71m and 83.3kg.

Procedures: This is a retrospective study; all retrieved data was de-identified before analysis. Body mass was measured without the TTP. TTP mass was measured with the suspension system and shoe. Residual limb length (RLL) was measured from the patella tendon to the distal end of limb.

Data Analysis: Descriptive statistics were used to derive relationships between TTP mass, body mass, and contralateral side mass. The contralateral side mass was calculated two ways 1) as 6.18%[1] of the user's body mass, representing complete shank and foot (CM) and 2) as 3.26%[2] of user's body mass, representing estimated mass of the lost limb segment (MLL). Body mass index (BMI) was computed and subsequently data was analyzed by BMI categories: normal, overweight and obese. To determine if differences exist among the BMI categories independent t-tests were performed with significance at $\alpha = 0.1$. Further, a Pearson Product Moment Correlation analysis was done for TTP mass and RLL.

RESULTS

Overall, the mass of a TTP is **2.6kg** which can be expressed as **3.2%** of body mass, **9.4%** of BMI, **51.6%** of CM and **97.6%** of MLL (Table 1)**.** The TTP mass as a % of body mass (*p=0.06*), BMI (*p=0.04*), CM (*p=0.06*) and MLL (*p=0.06*) was significantly greater between the normal BMI group, and the obese BMI group. RLL and TTP mass have a negative relationship, **r = - 0.25**.

Table 1. Prosthesis mass (PM) as a % of body mass (BM), BMI, CM and MLL by BMI categories

	PM (kg)	BM (kg)	PM as % of BM	BMI (kg/m^2)	PM as% of BMI	CM (kg)	PM as % of CM	PM as % of MLL
Normal (18.5 to 24.9kg/m^2), n = 4								
Mean	2.3	65.9	3.5% *	21.6	10.7%*	3.4	56.8% *	107.7%*
Range	1.8-2.7	60.6-78.1	2.3-4.3%	18.5-24.0	7.6-13.5%	2.3-3.9	37.6-69.8%	71.3-132.4%
Overweight (25 to 29.9kg/m^2), n = 4								
Mean	2.9	82.6	3.5%	28.3	10.3%	5.1	56.5%	107.2%
Range	2.0-4.1	75.1-95.3	2.7-5.4%	25.4-29.3	7.0-16.1%	4.6-5.9	44.0-87.2%	83.4-165.3%
Obese (>30kg/m^2), n = 4								
Mean	2.5	101.1	2.5%	35.4	7.0%	6.2	39.9%	75.7%
Range	1.8-3.2	77.1-129.8	2.4-2.7%	30.1-42.3	6.0-7.5%	4.8-8.0	38.1-43.3%	72.2-82.1%
All groups combined, n = 12								
Mean	2.6	83.3	3.2%	28.4	9.4%	5.1	51.6%	97.6%

** - Normal BMI group significantly different than Obese BMI group, p < 0.1*

DISCUSSION

There is a lack of evidence on the relationship between a user's body and TTP mass. This preliminary investigation has yielded ranges for relationships between TTP mass, body mass, BMI, CM and MLL of users (Table 1). The values found here for TTP mass as % of body mass are larger than past reports[3,4], which could be because TTP mass in this study was taken with the suspension system and shoe. An analysis of the sample by BMI revealed that all TTP mass and user relationships change across the 3 categories, with significant difference between the normal and obese BMI groups. Interestingly, TTP mass was similar for the 3 BMI categories, but on analyzing TTP mass as a % of all other variables (Table 1) it was found that individuals with normal BMI have a relatively heavier TTP, compared to those with obese BMI. Further, the TTP mass was found to be 75.7 to 107.7% of MLL. RLL was inversely related to TTP mass; the longer the TTP the less it weighs. Future studies should review data on a larger sample size and utilize a variety of clinics & clinicians to gain a better insight into TTP mass and user relationship.

CONCLUSION

The TTP mass and user relationship is different for each BMI group. Knowledge of this difference may make it more convenient for clinicians when deciding on the initial TTP mass.

CLINICAL APPLICATIONS

Clinicians should aim to keep their patient's TTP mass around 3.2% of the body mass. This, however, may change based on the patient's BMI.

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Phantom Pain: Noninvasive Microcurrent Pain Management- Acuscope-Myopulse

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INTRODUCTION

Two types of pain are common following amputation: phantom limb pain (PLP) and/or residual limb pain (RLP)[2]. Regardless of the time from amputation, phantom pain is the most frequently reported type of pain in amputees, and 70-80% of patients report experiencing significant or severe pain[2]. The effects of this pain can be debilitating, negatively affecting quality of life, relationships, and the ability to work, along with an increased risk of depression[2]. Poor pain management can further impair function by preventing amputees from using prostheses. Medicinal options for treating post amputation pain are often unsatisfactory, with negative side-effects and potential for addiction, and/or misuse[1&2].

Current effective methods for delivering electrical stimulation for PLP treatment are cumbersome, requiring electrodes placed in precise locations[2]. Further, patients can expect extreme discomfort during treatment. Other treatments include invasive surgeries and electrodes that need to be worn for days [2].

An Electro-Acuscope is a Transcutaneous Electrical Nerve Stimulation (TENS) device that produces microamperage designed to help restore damaged tissue. Incorporating bio-feedback with a myopulse instrument, this device is programmed to monitor electrical levels in tissue and deliver appropriate microamperage based on the bio-feedback[3]. This study investigates the potential of the use of an Acuscope for reducing PLP and RLP, where electrical stimulation is administered on the skin and no adverse side effects or high level discomfort is anticipated.

METHOD

Subjects: Adult patients between the ages of 35 and 75 years old who have experienced PLP and/or RLP for at least one year.

Apparatus: Electro-Acuscope and Myopulse bio-feedback.

Procedures: Subjects will complete a pre-treatment Short Form McGill Pain Questionnaire and a Visual Analog Scale (VAS) for pain. Up to ten treatments will be administered with the Electro-Acuscope and Myopulse instruments. Following each treatment, subjects will be asked to complete a Pain Outcomes Questionnaire – Short Form pain survey, and three months after their final treatment. Surveys were selected based on existing validation[4].

Data Analysis: Appropriate statistical analysis for interval and ratio scales will be used to determine statistical significance in changes to perceived pain levels.

RESULTS

Results will be based on patient self-reports, Three surveys will be used to obtain both interval and ratio level data.

DISCUSSION

In 2005, the estimated number of persons in the United States living with limb loss was 1.6 million and that number is estimated to climb to 3.6 million by 2050.[5] It is to the benefit of patients, clinicians, and researchers to continue investigating treatment options for a growing population living with amputations, and suffering from PLP and/or RLP.

CLINICAL APPLICATIONS

This research can be useful for clinical purposes, by studying a potential non-invasive treatment option for patients who are either concerned with side-effects or discomfort with current available treatments, or are not satisfied with previous outcomes. Acuscope and Myopath instruments can be operated by one person, and are transportable.

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Plastic Waste in Orthotic and Prosthetic Fabrication Labs

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INTRODUCTION

Plastic consumption has escalated with an average growth rate of 5-6% per year, worldwide, which has subsequently lead to the continuing rise of plastic waste (Saisinchai, 2011). Unfortunately, the majority of plastic waste ends up in landfills; in 2006, of the 2.7 million tons of plastic polyethylene terephthalate (PET) bottles on U.S. shelves, fourth-fifths were deposited in landfills (Intagliata, 2012). The growth of landfills poses detrimental consequences to environmental problems, as the decomposition process of plastic can take anywhere between 10 to 30 years, (Saisinchai, 2011). The allied health profession of Orthotics and Prosthetics incorporates a wide variety of plastics in the fabrication of orthoses and prostheses due to their desirable characteristics of being rigid, easily machined, easily thermo-formed, and lightness (Wang, 2015).

Throughout the fabrication process there is a buildup of excess plastic that is ultimately thrown away. Fabrication labs and other practices are incurring unnecessary expenses from the loss of excess waste. However, although recycling seems easy on the surface, there is an ongoing debate as to whether in-house recycling is actually a worthwhile practice, which is evident by the limited research into the application of recycled materials in O&P (Ramayah,2012).

The purpose of this research is to determine the amount of plastic waste the goes unused in the fabrication of orthoses and prostheses. Furthermore, to investigate the cost of excess waste and explore the best alternatives to either reduce, or reuse in-house waste.

METHOD

Subjects: Three central fabrication O&P labs.

Procedures: Sheets of plastic used to fabricate orthotic and prosthetic components will be followed in the fabrication process to determine how much plastic goes unused in a central fabrication lab. The initial, unused, sheet of plastic will be weighed using a standard scale. The sheet will then be followed as it goes down the line. The component(s) that are made with the initial sheet of plastic will be recorded and then weighed before any accessories are added. With the initial weight and the final weight, a percentage of plastic that went unused will be determined. A total of ten sheets of plastic from each lab will be followed to obtain an average of plastic waste produced.

Data Analysis: Data from each lab will be analyzed and compared. Total waste (in weight) per year will be analyzed based on the average consumption of plastic of each plant. The estimated costs of the wasted plastic will also be determined.

DISCUSSION

It is expected that the fabrication of orthotic and prosthetic components produce a significant amount of plastic waste. This waste is contributing to the excessive build up of plastic in landfills. This waste may also add unnecessary cost to the fabrication of orthotic and prosthetic devices. It is expected that the waste produced will be significant in the overall cost of the facility. In multiple case studies analyzing the cost benefits of recycling it was found that companies such as Anheuser-Busch saved a significant amount of money by implementing a recycling system (New Jersey Waste Wise, 2015). Based on projected data from O&P fabrication labs, there may be significant savings benefits for decreasing plastic waste. By bringing attention to the amount of plastic waste that is being produced, possible solutions can be explored. Recycling unused plastics is beneficial both economically and environmentally.

CONCLUSION

O&P fabrication labs produce a significant amount of plastic waste. The waste can potentially be recycled into other plastic components used in the fabrication process, and consequently increase the over all savings of the lab and decrease environmental hazards.

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PRELIMINARY STUDY: RESIDUAL LIMB PAIN, PHANTOM LIMB SENSATION, PHANTOM LIMB PAIN AND PSYCHOLOGICAL WELL-BEING OF AMPUTEES IN THAILAND

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INTRODUCTION

National survey in 2003 reported approximately 120,000 amputees from the population of 63 million people in Thailand. Obviously, the amputation highly affects the amputee in terms of physical ability, psychological changes and social participation.

Most of the patients experience the residual limb pain, phantom limb sensation and phantom limb pain after amputation, which not only affect to their functional ability, but also psychological well-being, leads to a lower quality of life. The data from this study provided benefit for the amputees in Thailand in terms of better knowledge, and also for the health care team for better rehabilitation provision.

METHOD

A cross sectional survey using responses from 132 amputees at Sirindhorn National Medical Rehabilitation Center was conducted.

Participants were interviewed individually by the prosthetists. The outcome measures; The outcome measures for the ressidual limb pain (RLP), phantom limb sensation (PLS) and phantom limb pain (PLP), were the Amputee Questionnaire (Wartan et al., 1997) and Short-form McGill Pain Questionnaire (SFMPQ) (Melzack, 1987). Psychological well-being, mainly focused on anxiety, depression and quality of life, were assessed by using Thai Hospital Anxiety and Depression Scale (Lotrakul, 2001) and WHOQOL–BREF–THAI (Mahatnirunkul et al., 2002).

All statistical analysis was conducted by using PASW Statistics (SPSS) 12.0 (SPSS Inc., Chicago, IL., USA). Descriptive statistics was used to analyze the demographic and post-amputation data. Chi-Square, Point Biserial Correlation and Pearson's Correlation tests were utilized to analyse the correlations among variables. The p-value of less than 0.05 was considered a statistically significant difference.

RESULTS

The present study demonstrated that RLP, PLS, and PLP were commonly experienced by 40.9 %, 67.4 %, and 37.9 % of amputees, respectively. Number of amputees with experience of all 3 phenomenon and amputees without experience of all 3 phenomenon were similar (25.8 % and 23.5 %).

The subjects reported the significantly decreased in PLP after many years post amputation. The outcome of psychological well-being scores for anxiety and depression after amputation were similar. More than 90% of amputees reported no anxiety or depression problem. Sixty percent of amputees reported the medium level of quality of life. There was a significant positive correlation between RLP, PLS, and PLP. Moreover, a positive relationship was also found between these three variables i.e. RLP, PLS, and PLP, and anxiety; PLS and depression; PLS and quality of life. Interestingly, the result in the current study, which was different from previous studies in some aspects, is possibly due to the sample and study design.

	Depression	Anxiety	Quality of life
RLP	**.178***	.041	-.046
PLS	**.251****	**.183**	**-.194***
PLP	**.173***	.108	-.163

*p<.05, **p<.01

Table 1. Correlations among RLP, PLS, PLP, depression, anxiety, and quality of life

CONCLUSION

Limb amputation affects the amputee in terms of physical ability, psychological changes and social participation. This study demonstrates the similar data to the previous studies in other countries related to the RLP, PLS, and PLP phenomenon. The finding suggested the importance of the post amputation phenomena assessment and management.

CLINICAL APPLICATIONS

The current study also suggested that clinicians should provide information concerning PLS and PLP to amputees and family. Further research utilizing longitudinal study to observe the long term experience of RLP, PLS, and PLP, and psychological well-being of amputees is recommended.

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STUDENTS' EXPECTATION: SIRINDHORN SCHOOL OF PROSTHETICS AND ORTHOTICS, MAHIDOL UNIVERSITY

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INTRODUCTION

To understand students' expectations of orthotic and prosthetic education program is one of the priorities for Sirindhorn School of Prosthetics and Orthotics (SSPO), Mahidol University Thailand. Student expectations are a valuable and constructive source of information. The knowledge of student expectations can help the lecturers to design of teaching programs and the education organization to sustain the quality of the educational and supportive service.

The purpose of this study was to explore the educational and professional expectation of the P&O undergraduate students of Sirindhorn School of Prosthetics and Orthotics, Thailand.

METHOD

The cross-sectional survey study was conducted during the first month of academic year 2013-2014 and 2014-2015. The convenient sample of P&O undergraduate students of Sirindhorn School of Prosthetics and Orthotics, Mahidol University, were requested to indicate, on a self-complete questionnaire, how important they consider each of the factors to be in determining their expectation of the P&O education service they are receiving at the university. The questionnaire composed of 21-item questions on a Likert type scale and one opened-end question. Items were based on expectation of lecturer and teaching methods, instructional media, service and supporting system, and after-graduation concerns. Perceived importance was used as a vital indicator of expectations.

All statistical analysis was conducted by using PASW Statistics (SPSS) 15.0 (SPSS Inc., Chicago, IL., USA). Descriptive statistics was used to analyze the demographic data, and educational and professional expectation of the P&O undergraduate students

RESULTS

Data collection was done in two consecutive academic years. A convenient sample of 85 (77%) and 93 (85%) freshman, sophomore, junior, and senior P&O undergraduate students in academic year 2013-2014 and 2014-2015, respectively, enrolled in this study. The findings indicate that students want lecturers to be knowledgeable, attentive, enthusiastic, and approachable. Students expect for the instruction media and library service to support the learning needs. Students predominately want to gain P&O knowledge and experiences to be able to pass examinations and to be prepared for their profession. This study also shows that students' expectation to be able to participate and be acknowledged in the multidisciplinary rehabilitation team. The comparison of expectation among those four groups of students was analyzed. Some educational and professional concerns were raised from students.

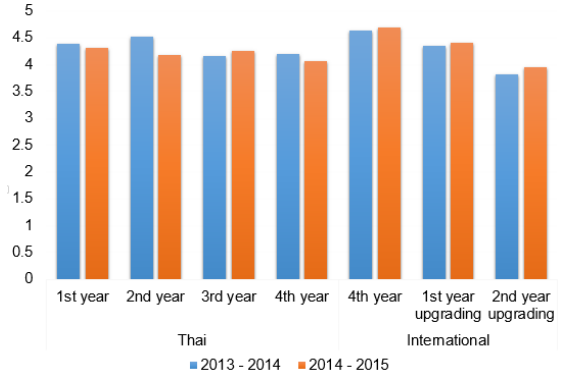

Figure 1. Average scores of students' expectation in 2 academic years

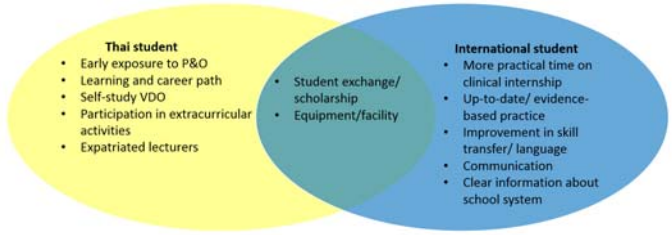

Figure 2. Educational and professional concerns from Thai and international students

DISCUSSION & CONCLUSION

The findings suggest that student expectations in general P&O education and supportive services are relatively similar in all level of student and stable over time. The study also indicates that lecturers should acquire the desired attributes for knowledge and experience transfer. The approach of teaching in each level of student should be taken into consideration by reflecting the expectations, needs and values of students. Other aspects were also discussed.

CLINICAL APPLICATIONS

N/A

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Tensile Strength of Materials used in 3D Printed Prosthetic Sockets

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INTRODUCTION

The application of 3D printing to the field of Orthotics & Prosthetics is advancing rapidly. This technology has been used to successfully fabricate transtibial sockets, nasal prostheses and transradial prostheses (Hsu et al. 2010, Palousek et al. 2014, Gretsch et al. 2015). Knowledge of the strength and durability of the materials used to print sockets using 3D technology is vital for determining which materials to use (Gerschutz et al. 2011), as safety and effectiveness are critical considerations. Because of the impending changes in the reimbursement system, which could affect the products that an O&P practitioner can offer, 3D printing may play an increasing role in O&P by offering patients a broader array of customized devices.

METHOD

The primary goal of this study was to test the tensile strength of a standardized prosthetic socket fabricated using three different materials on a 3D printer, compared with previously published results using conventional fabrication methods. The second objective was to compare the time and cost associated with each method. We used a previously generated 3D model of a transtibial socket used in a study by Gerschutz et al. 2014 as the standardized model. The materials used in our tests were carbon fiber infused ABS filament, polycarbonate (PC-Plus), and ABS. All three materials were processed on the same Rostock Max V2 printer and tested for static failure as well as tensile strength.

Procedures: This study will replicate a prior study performed by Gerschutz, Haynes, Nixon and Colvin. However this study will be testing materials used for a 3D printer and will be considered a definitive socket.

Data Analysis: Statistical analysis will be conducted on the tensile strength and impact values according to ASTM Standard D256 and D638 with a one-way analysis of variance with a 5 percent significance level.

RESULTS

This project will report on the amount of tensile strength and the impact break classification for each of the three materials based on information gathered from studies done by Gerschutz et al. 2011 and 2012. The results concluded by Gerschutz et al provided a significant difference between the three types of socket materials used. Carbon fiber provided the highest tensile strength at yield point comparatively (Gerschutz et al 2011). We similarly expect the carbon fiber filament to produce a higher tensile strength at yield compared to the PC-Plus and ABS filaments.

Figure 1.Transtibial Sockets made using the Rostock Max V2 printer. The left image was made using the PC-Plus filament and the socket in the right image was made using ABS.

DISCUSSION

The application of 3D printing is making extreme advances. There is little information on the strength and durability of the materials being used to print prosthetic sockets. It is essential to evaluate these materials to ensure that the best product is being provided.

CONCLUSION

With the increase of technology and decrease in cost, 3D printers are becoming more accessible to the public. If carbon fiber 3D printers were implemented in daily use for prosthetics, time and cost could be cut down drastically. It is in the patient's best interest to be able to create a socket using the best material on the market at a price they can afford.

CLINICAL APPLICATIONS

The findings from this project will be useful in a clinical setting when deciding which process to use to fabricate a definitive socket, as well as, which material to use that will be less time consuming and costly but efficient at the same time.

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USE OF ELECTRICAL STIMULATION ON RIGHT EXTREMITIES OF AN ADULT WITH SPASTIC TRIPLEGIA

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INTRODUCTION

Patients with spastic cerebral palsy (CP) have difficulty with motor control and frequently use ineffective movement patterns. Both the integrated volitional control electrical stimulator (IVES) and the functional electrical stimulation (FES) have been used to facilitate the proper muscle group at the proper timing. This case report describes to evaluate the efficacy of IVES and FES treatment in an adult with spastic CP triplegia.

METHOD

Subject : We present an 19-year-old girl diagnosed with CP triplegia (Gross Motor Function Classification System level Ⅲ), without cognitive impairment. She was able to ambulate indoors with a walker, and used an electric wheelchair for long distances. Her main complaints were stiffness and pain of right upper muscles, difficulty in prolonged standing and walking, and toileting.

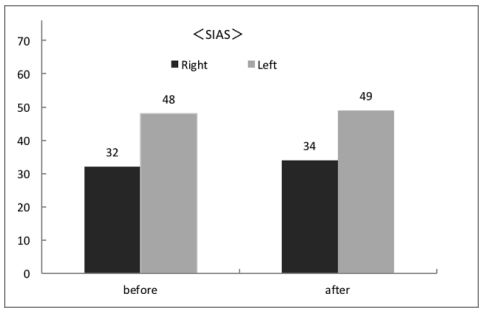
Apparatus : We used the IVES system (MURO Solution, pacificsupply, Osaka, Japan) to elicit right wrist and finger extension during voluntary movements, and the NESS L300 Plus neuroprosthesis system (Bioness Inc., Valencia, CA, USA), which delivers electrical stimulations to the right common perneal nerve.

Procedures : IVES therapy sessions were undertaken for 10-12 hr/day for 12 days, including during therapy sessions and daily activities. FES was used to stimulate the right dorsiflexors muscles and improve equinus foot at the swing phase for 30min-1 hr/day for 12 days.

Data Analysis : The assessment was conducted using Simple Test for Evaluating Hand Function (STEF), Stroke Impairment Assessment Set (SIAS) and Functional Independence Measure (FIM).

RESULTS

All scores showed a slight increase with the right side； the score of STEF was from 1 before the intervention to 3 after intervention, and the score of SIAS was from 32 before the intervention to 34 after intervention. Nevertheless it was improved without statistical significance, she was able to use as a functional assistive hand little by little, so the score of STEF with the left side was from 80 before the intervention to 86 after intervention. Furthermore， she was gradually able to keep her right foot on the footrest for her electric wheelchair and the sitting posture was improved than before.



DISCUSSION

Neuromuscular electrical stimulation （ NES ） has been used successfully to increase muscle strength and size, and temporarily reduce spasticity. Although a short time intervention, the patient was interested in a new functional gain and motivated to change her conventional ineffective movement patterns. Further therapy are needed for her to gain a functional assistive hand and improve equinus foot.

CONCLUSION

This report suggests that NES may be effective for adult spastic CP. Further studies are needed in order to validate our intervention.

CLINICAL APPLICATIONS

This therapy has many potential clinical applications in patients with spastic CP.

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Dynamic Bracing for Contracture Management

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INTRODUCTION

Contracture management has been one of the more difficult challenges we face as orthotists. Joint stiffness or contractures may be caused by immobilization following surgery, disease or trauma. Joint contracture is associated with reduced range of motion (ROM) due to structural changes in non-bony tissues, including muscles, tendons, ligaments and skin. Ensuring optimum results for our patients in order to prevent surgery or regain the biomechanics for ambulation and/or activities of daily living are what we strive for and expected of us. How can we achieve such results? What are the key factors necessary in order to provide the best possible outcome? This case study will focus on using low- load prolonged stretch (LLPS) protocol with the use of a dynamic knee extension orthosis. (DKEO)

PATIENT PROFILE

Patient is a 28 year old male involved in MVA in 2014 resulting in incomplete spinal cord injury at T12. Standing at 5'6" and weighing 158#, patient presents with bilateral lower extremity weakness and paralysis. MMT for lower limbs is 0 with hips at 3-. Patient is unable to stand or walk independently. He is mobile with the use of wheelchair. Patient received limited rehab services post MVA, spending most of his time in wheelchair. As a result, patient now has -25 degree soft tissue knee flexion contracture of right knee.
(See Figure 1)

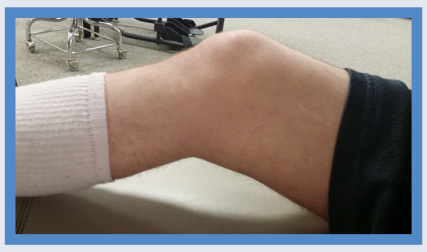

Figure 1, -25 degree knee flexion contracture

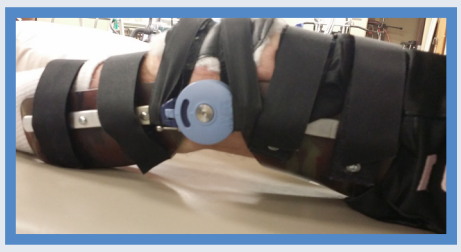

Figure 2. Dynamic Knee Extension Orthosis

GOALS

Patient had started to undergo regular outpatient physical therapy and was highly motivated to walk again. Physical therapy goals were to eliminate knee flexion contracture in order to begin working on independent standing and possibly ambulation. Orthotic goal was to provide a dynamic stretch over time to get the most productive and safe stretch possible.

METHODS

An orthosis design for treating extension contractures that gradually increases range of motion. The thigh and calf cuffs were custom fabricated using 3/16" polypropylene and joined with a lateral Multimotion size regular corrective joint that permits gradual torque/force adjustment from 0 to 90 inch pounds, a medial MultiMotion size regular free motion joint to provide the desired torsional stiffness to the orthosis, and an anterior knee cap to create three point system for application of force. (See figure 2). The custom knee orthosis was used during night-time hours to provide LLPS in order to gain optimum results while measuring ROM weekly to ensure ROM increased over eight week period.

PROCEDURE

Starting tension set at 4 (See figure 3). The typical starting range is between 2 and 4. When using regular size Multimotion corrective joint, value should be set to sub-maximum spring tension (SMST) the patient can tolerate for a time period of 7-8 hours a day. After initial acclamation period patient wore KEO for 10-12 hours a night. Patient was followed up on a weekly basis, testing ROM of the knee. As long as there was an increase of ROM the tension remained set to 4. When a plateau was reached, tension was increased to new SMST.
(See figure 4 – Weeks 4 & 5)

Figure 3. Tension adjustment started at 4

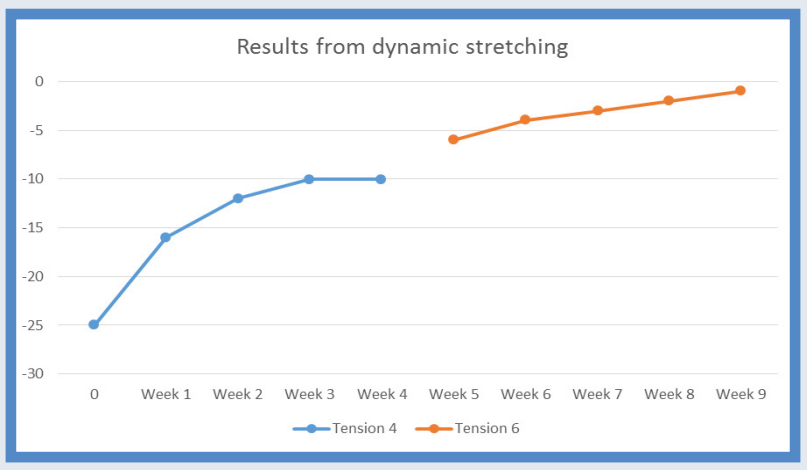

Figure 4. Knee Extension ROM

RESULTS

ROM was recorded on a weekly basis during the patient's therapy session by the physical therapist. It was observed that best results came the weeks after a tension increase. The greatest increase occurred during week 1 (See figure 4). Patient is now able to fully extend knee and can begin working on standing during therapy.

DISCUSSION

After conducting this case study it is evident that dynamic splinting for contracture management is a viable, noninvasive and non-stressful treatment. However, we face several challenges in order to achieve desired results such as compliance, proper follow-up and knowing when to provide such orthosis. The intention of the study is to instill confidence and knowledge to achieve maximum outcome using a DKEO

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ACKNOWLEDGEMENTS

Jeff Barrett PT

Pediatric Partial Foot Prosthesis: A New Treatment Option

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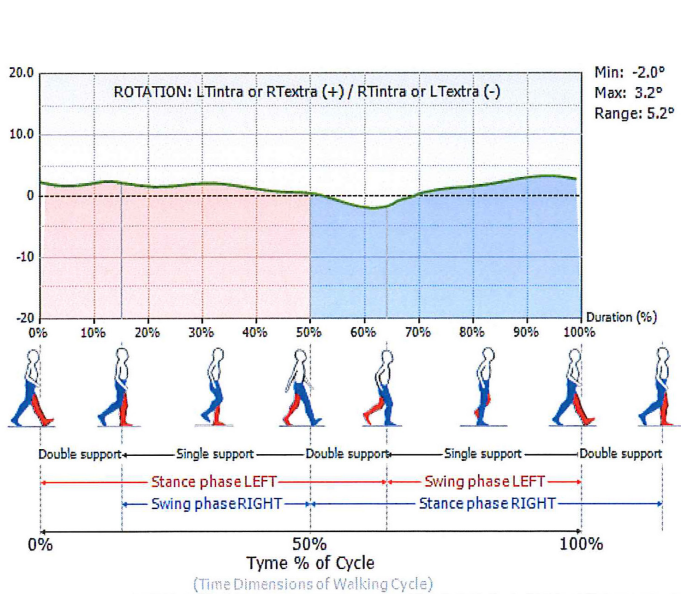
INTRODUCTION

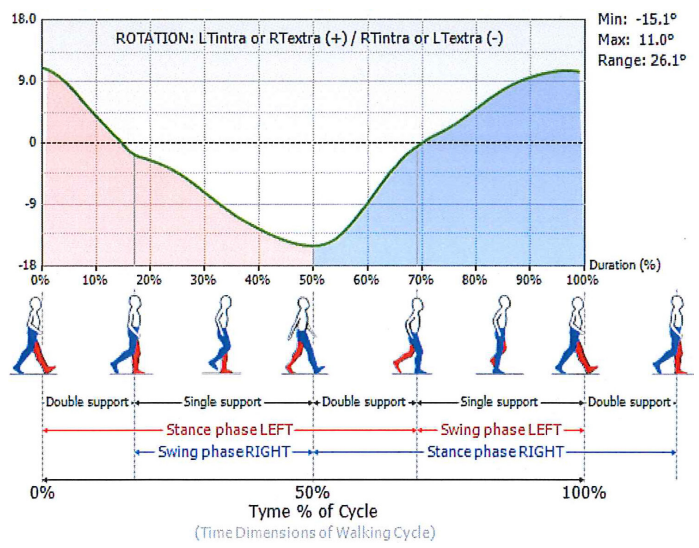
Documentation of pediatric partial foot amputation (PFA), prosthetic intervention, and effectiveness of treatment is insufficient. However, recommendations regarding pediatric prosthetic intervention advise downsizing, sequenced complexity, and a modular design that does not interfere with an increased activity level.[2] In the general population, PFA is the most common amputation surgery with 2 per 1,000 affected.[4] Transmetatarsal or mid-tarsal amputations account for approximately 24% of PFAs.[3] In the pediatric population, 40% of amputations are attributed to trauma.[8] Lawn mowers and household accidents account for the majority of the partial foot amputations in the pediatric population.[8] Current pediatric treatment options mimic those for adults with the extent of the intervention proportional to the extent of tissue lost.[3] More recently, it has been recommended that any amputation involving the metatarsal heads or proximal structures requires a prosthetic intervention that extends proximal to the ankle.[6] A prosthesis utilizing a custom-fit rigid dynamic carbon composite (DCC) ankle foot orthosis structure to aid in the restoration of gait has been proposed for the adult PFA patient.[7] By extending above the ankle, the prosthesis aids in the progression of the center of pressure along the foot and restores the biomechanics of walking.[6]

METHODS

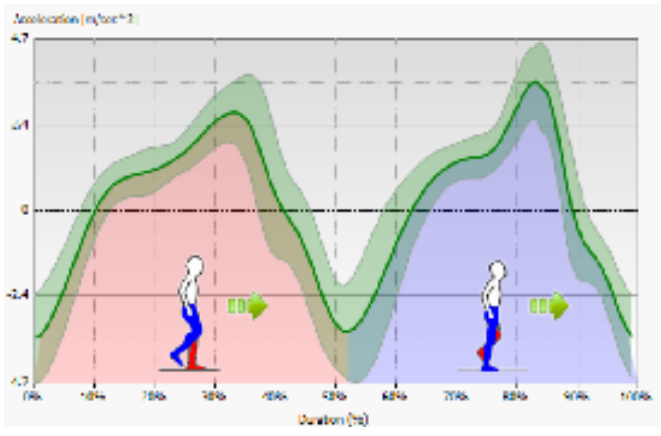
A prosthetic design for treating the pediatric partial foot amputee that restores gait function by addressing the biomechanical deficits is proposed. A custom fit rigid DCC AFO with carbon anterior shell, customized with a toe filler type socket with wedging, lifts, and posting are the components of the proposed prosthesis. Until recently, there was not a custom-fit option for providing a reliable custom-fit rigid DCC structure in which to fabricate a custom prosthesis for the pediatric population. The new custom-fit rigid DCC is a prefabricated full carbon foot plate, rigid lateral strut, and carbon composite anterior shell. The footplate is rigid with a tapered rocker built into the distal section with a flexible posterior section and a rigid stable midfoot. This design aids in restoring gait by allowing for a controlled plantarflexion moment at initial contact, a stable midstance, and a controlled tibial advancement through terminal stance, while maintaining a 3rd rocker rollover and providing propulsion at terminal stance. This system is combined with a custom-molded toe filler type prosthesis that is aligned with wedges, posts, and lifts to maximize functional outcomes. This system addresses the biomechanical deficits of the PFA and the DCC is designed to have varying degrees dynamic function by style and size. The ability to customize the socket, alignment, and interface helps to protect the skin of the residuum while the dynamic function can be customized for functional needs.



Pelvic Rotation Graph:Toe Filler Insert Only



Pelvic Rotation Graph: KiddieROCKER™ With Toe Filler Insert



PATIENT PROFILE

VA is a 6.8-year-old female, 42" tall, and weighing 45 lb with congenital longitudinal amputations of both distal lower and upper extremities and no other co-morbidities or congenital malformations.

Her intact lower extremity residual limbs are formed by the calcaneus, talus, cuboid, 4th and 5th metatarsals, and the 5th phalanges with a nub distally – her lower limbs appear to be symmetrical in appearance. Dorsiflexion MMT strength test 5/5 bilaterally. Plantarflexion MMT strength 3/5 bilaterally with the patient able to rise onto the residual lateral toes.

She does not normally wear any orthosis or toe filler but uses a high top athletic type shoe to help contain and reduce skin irritation on the medial aspect of her ankle, which is the very prominent aspect of the medial talus.

It is recognized that her normal ambulatory status is without orthotic/prosthetic intervention and that the tested interventions of an anterior shell dynamic carbon composite AFO (AKA: KiddieROCKER™) with an incorporated custom toe filler socket and a toe filler alone were a new condition for the test subject and she did not have an opportunity beyond walking in the office to accommodate to the introduced interventions.

However, we found that she was able to accommodate between each test intervention and ambulate without difficulty. We used the BTS G-WALK gait analysis system to measure temporal-spatial aspects of gait and pelvic girdle angles. We compared data collected with the 2 orthotic/prosthetic interventions to data collected with the subject wearing her high top shoes.

DISCUSSION

Research on specific effects on gait function utilizing the proposed PFA DCC design need to be conducted. Preliminary data regarding use of the DCC AFO in the pediatric population indicates that a dynamic response carbon AFO, similar to the rigid DCC design, provides improved function in running, jumping, and walking performance while Gross Motor Function Measure was also improved.[1] Similar outcomes are expected with a PFA DCC prosthesis due to the similarity of the gross structure and function of the rigid DCC design.

RESULTS

The pediatric prosthetic design is proposed based on the outcomes of the adult treatment option with similar outcomes expected. This prosthetic design has been used with adult PFA patients since 2010 and the anecdotal results are positive. Patients report increased mobility and decreased skin breakdown.

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ACKNOWLEDGEMENTS

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DISCLOSURE

Vincent DeCataldo, BOCPO, NJ LPO is employed by Allard USA, manufacturer of dynamic carbon composite AFOs.

allard USA

Maximizing Functional Outcomes Utilizing Objective Gait Analysis – A Case Study

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INTRODUCTION

Charcot-Marie-Tooth (CMT) is one of the most common inherited neurological disorders, affecting approximately 1 in 2,500 people in the United States. The neuropathy of CMT is a slowly degenerative process with symptoms often starting in adolescence or early adulthood and typically results in weakness of dorsiflexors, plantarflexors, and the intrinsics of the feet. CMT is not considered a fatal disease and people with most forms of CMT have a normal life expectancy; however, they typically require physical therapy, orthotic intervention, and assistive devices to maintain mobility during their lifetime.[1] Identifying maximal functional outcomes is often limited to visual gait analysis and subjective patient commentary, making difficult to know if an adjustment or change of design has made a difference to function. Utilizing a portable computerized gait analysis system, we are able to use quantified measures of gait to modify our components, designs, and gait training to maximize functional outcomes of orthotic intervention.

METHODS

A single female patient with a 15-year history of CMT affecting bilateral lower extremities was tested in 3 different bilateral conditions. The custom-fit dynamic carbon composite AFO designs included 1) without adjustment; 2) with increased rigidity without adjustment; 3) same rigidity as condition 2 with an adjustment to customize the orthosis for the heel height of the shoe. Temporal-spatial and pelvic motion data was collected utilizing a BTS G-Walk Portable Gait Analysis System placed at the L5 vertebral level.[2] Speed, percent of double-limb support, and pelvic kinematics were compared across the conditions and to normal values for women.

PATIENT PROFILE

VM is a 39-year-old female, 5'0", 113 lb, with Charcot-Marie-Tooth disease. She was diagnosed about 15 years ago with prominent symptoms of bilateral parasthesia and weakness in hands and feet. She does not have the typical cavus foot profile; instead, she has bilateral midfoot pronation and calcaneal valgus. Currently, she presents with bilateral dorsiflexion strength of 3+/5, plantarflexion strength of 4/5, and knee extension strength of 4/5.

She was initially fit with bilateral custom posterior leaf spring AFO's (approximately 7 years ago). She rejected the custom orthoses because they caused sores on her feet and she felt that it took more effort to walk with the orthoses than it did without. One year ago, she started wearing the Allard ToeOFF® AFO's and felt that they assisted her with activities involving long distances, but for day-to-day wear, she used an elastic ankle support. She also had tried the BlueROCKER™ AFO's and the Ypsilon™ AFOs. She uses each Allard USA orthosis for a variety of activities and changes to give her more or less support and propulsion based on the activity. Currently she walks, runs, trail hikes, and practices yoga on a regular basis.

DISCUSSION

Comparing objective measured values provides guidance for providing the orthotic design with maximum functionality for the patient. Utilizing the G-Walk system, functional outcomes due to changes in orthotic design and customization can be measured and documented. The orthotic intervention that provides the maximum function for this patient allowed for increased speed and decreased pelvic motion, which happened to be the more rigid design customized for shoe heel height. By utilizing a portable computerized gait analysis system, changes in gait function can be monitored over time and with changes to orthotic intervention as well as physical therapy treatments.

RESULTS

Speed and percent double limb support were closest to normal values when the patient ambulated with the orthoses that were more rigid, custom fit, customized for heel height and manufactured fully of carbon composite. Pelvic range of motion in 3 planes shows that orthotic interventions with more rigid profiles reduce pelvic motion primarily in the transverse plane.

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ACKNOWLEDGEMENTS

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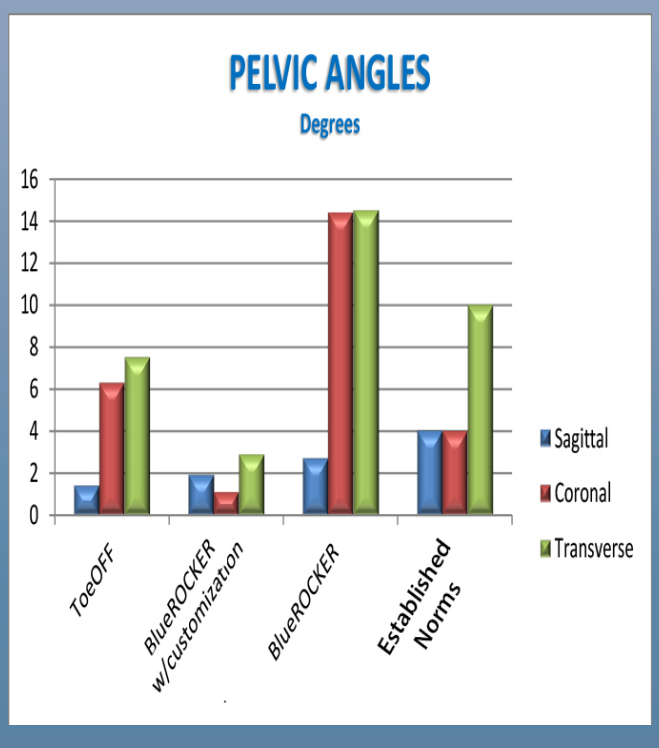
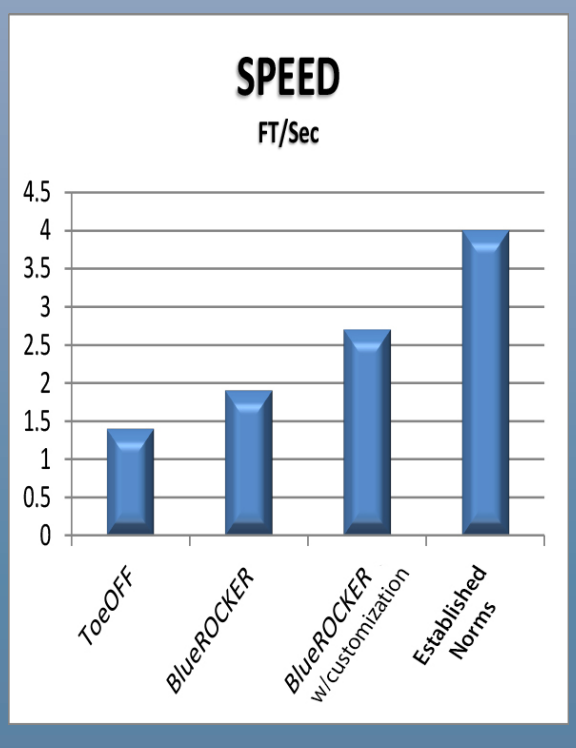
DISCLOSURE

Vincent DeCataldo, BOCPO, NJ LPO is employed by Allard USA, manufacturer of dynamic carbon composite AFOs.





3D Printed Dexterous Prosthetic Foot Control and Structure Design

Zachary Stewart, Kevin Hutchens, Matthew Gordon, David Manzenburger
University of Southern Maine

INTRODUCTION

This project focuses on the analysis and design of 3D printed lower limb prosthetic structures. Throughout the teams research the discovery that options for materials to build the structure of the prosthetic foot were very limited. The major choices are 3D printed plastics, carbon fiber, titanium, steel and aluminum. The team has also done a large amount of research into 3D printing and has decided to prototype the final design using a 3D printer. The major reason for this is that it allows for a product to be manufactured fast and very easily. The features that have been designed and built are the ball of the foot, structural bars, heel and central ball. This prosthetic foot is load bearing but has not been tested with human subjects. The team has also conducted material strength test of 3D printed Materials. With the use of 3D printers, the team has printed six different configurations of materials.

METHOD

Apparatus: Makerbot 2X, Instron 5882, Tinius Olsen compression/tension tester, SolidWorks Educational Edition

Procedures: Standard samples were produced from ABS, PLA, and PLA-Carbon Fiber composite by Fused Deposition Modeling (FDM), then were drawn by an Instron 5882, and the resulting data was plotted for clarity. A material was chosen to proceed, and a design was created to utilize the properties of that material. A safety factor of 3 was chosen.

Data Analysis: Toughness, Elasticity, and Plasticity were assessed by 0.2%-strain method.

RESULTS

The final structure using the data collected from the materials study was tested to 534 pounds on the hydraulic compression tester. This number comes from the constraint that the average person weighs 178 pounds and with a safety factor of 3.

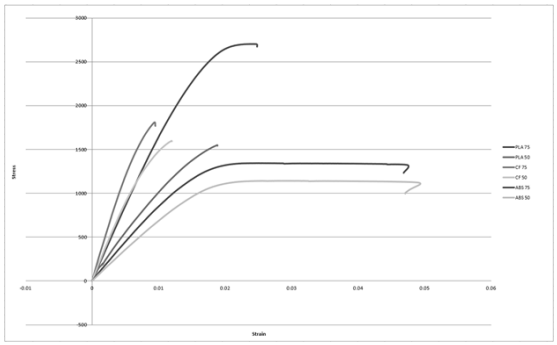


Figure 1: Stress versus strain chart of the six 3D printed configurations that were tested.

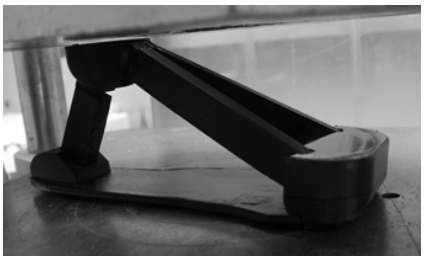


Figure 2: 3D printed model in compression tester

DISCUSSION

Through conducting the materials study the team learned about the material characteristics of FDM thermoplastics. These included carbon fiber impregnated PLA, ABS, and PLA as a standalone material.

CONCLUSION

After testing the three types of materials for overall strength, the standard ABS proved to the most effective for our project. The final structure was able to withstand the safe 534 lbs. of compression with only minor plastic deformation.

CLINICAL APPLICATIONS

This is an ongoing project that will produce a novel prosthetic foot structure which is intended to replace the functions of a natural human foot.

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Upper & Lower Knee Ab/Adduction Moment Sensing

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INTRODUCTION

Knee Osteoarthritis (KOA) is estimated to affect over 13% of the US population older than 45 years of age (Turciewicz, 2014). Indeed, the lifetime risk of developing symptomatic KOA for Americans has been estimated to be 44.7% (Murphy, 2008). Knee abduction/adduction moment (KAM) is recognized as a primary marker of KOA progression. A 1% increase in peak external KAM has been linked to a greater than 6-fold increase in the risk of KOA progression (Miyazaki, 2002).

Due to high costs, and limited measurement granularity, established KAM measurement techniques are an impractical means for tracking KOA progression. Measurement of KAM is currently limited to gait laboratories, which utilize motion capture systems to determine knee moments (van den Noort, 2013; Cappozzo, 1995). KOA often takes decades to develop. Identifying statistically significant changes in KAM on a year over year (or more frequent) basis therefore requires a higher degree of granularity than current techniques offer. Other attempts at measuring KAM during free ambulation have neither achieved complete independence from lab measurements, nor generated significantly greater granularity (van den Noort, 2012; van den Noort, 2013).

In this work, a novel means of measuring KAM during free ambulation is presented, offering determination of KAM with high measurement accuracy and measurement granularity. We have developed an orthotic leg brace containing pressure sensors located on the inner and outer shank and thigh regions that measure side forces. From these side forces, we have measured the forces generated by the knee that are balanced by the legbrace.

METHOD

Subjects: We performed a preliminary test on a 75-year old male **not** being treated for KOA with the legbrace set to its passive mode of operation. The subject walked on a treadmill at 2.2 miles per hour with an average step length 23.434 inches and average step period of 0.6052 seconds. Legbrace side force sensors were sampled at 4,608 samples per second. Sensor measures were created by adding 12 successive sensor samples and recording them on the legbrace's non-volatile memory. Additional Gait measures logged included: knee angle, shank tilt angle, shank lean angle, heel pressure, ball-of-foot pressure, foot angle and torso support force supplied by the legbrace. *Apparatus*: Sensor data were stored in Gait measurements of the subject were also taken using the lab-based motion capture system.

Procedures: The subject walked on a treadmill while data were collected by the brace and laboratory motion capture systems. After testing, data were processed using Wolfram's Mathematica. Motion capture data were analysed using commercially available software.

RESULTS

The novel approach used in this work generated KAM measurements that were lower than those generated by traditional techniques. Plots of data collected by laboratory and PUUMA KAM measurement systems are given in Figures 1 and 2.

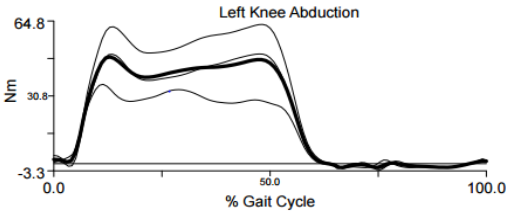
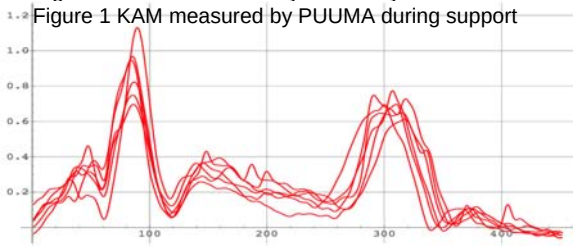


Figure 1: KAM measured by laboratory.

Figure 1 KAM measured by PUUMA during support



DISCUSSION

Our novel method for measuring KAM measures all discernable side forces exerted by the legbrace. These side forces began prior to heelstrike and peaked immediately following heelstrike and again prior to toeoff. Sensor calibration has not been completed preventing analysis of relative pressures between the brace and traditional methods.

CONCLUSION

The legbrace KAM measurements showed significant peaks not present in traditional KAM measurements. Further testing will be required to ascertain if these peaks are anomalous; peculiar to the brace/test; or are simply not detected by traditional methods. The potential for measuring KAM accurately and with the desired level of granularity is promising but unproven.

CLINICAL APPLICATIONS

The high accuracy and fine granularity side force measurements our method provides has the potential of creating a novel means of tracking/managing KOA.

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